IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CARDIAQ VALVE TECHNOLOGIES, INC., Plaintiff	)	
-VS-	)	CA No. 14-12405-ADB
NEOVASC INC., et al, Defendants	)	Pages 1 - 220

JURY TRIAL - DAY 3

BEFORE THE HONORABLE ALLISON D. BURROUGHS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 17
Boston, Massachusetts 02210
May 4, 2016, 9:34 a.m.

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I N D E X

P R O C E E D I N G S

THE COURT: Okay.

I got -- I have the two -- I don't know when these were filed, but they were here this morning, last night or this morning, doesn't make any difference.

The JenaValve motion I'm going to have to take some time to look back at my notes and just spend some time on.

The other one, which is Docket 426, CardiAQ bench memo seeking an instruction following Neovasc's opening. I'm happy to hear you on this. But I sat here and listened to the openings. I guess the distinction I would make is they can't argue ability to pay, but I think they can argue competitive forces. And I didn't hear yesterday, when I went back and looked at this with the excerpts this morning, what they said may come close, but I don't think that what they said crossed the line about what we were talking about during our motions in limine. I'm happy to hear you on it. As I say, in my mind, the distinction is the ability to pay, which your damage award should be affected by our size and shape and ability to pay and all that, versus they are doing this for competitive advantage. I don't see those things to be the same.

MR. SGANGA: Your Honor, the concern we've got is they did talk about shutting down the program, and the motion in limine that was granted was to preclude any argument about the

injunction or its potential impacts. So talking about shutting down Neovasc is in layman's terms for injunctive relief.

THE COURT: I didn't hear it that way. I really heard them to be talking about, you know, this is in lieu of competing in the marketplace. That sort of argument comes along with filing a lawsuit, right, they are filing this lawsuit for all these reasons.

MR. SGANGA: It's a hot-button defense issue in every IP case, your Honor. That's why we brought the motion in

09:39 limine, your Honor granted it. The concern is the jury shouldn't be put in the role of being policymakers about whether intellectual policy law is itself anti-competitive.

I agree with your Honor, to some extent, some discussion about competition is part of what we're doing, but to now talk about what the effect of plaintiff winning the case is, that's where they crossed the line.

THE COURT: I don't actually think that's what they did. I think what they did is they want to shut us down, which I'm sure is accurate.

09:40 MR. SGANGA: We want the jury to find liability on the causes of action and to enter a damage award.

Now, the point of what that -- what the consequence of that is, we're entitled to those remedies if the IP rights have been violated. But to now go the next step and suggest you're not going to get proper care from your physician because of

what we asked the jury to do --

THE COURT: I don't think they went that far, right.

The closest they came is you're going to put us out of business and patients won't be able to get our products. That's not even that, that's from the motion.

We're here because CardiAQ doesn't -- we're here because CardiAQ does not want to face competition from Neovasc.

MR. SGANGA: Your Honor, at page 91 of the transcript, quote, seeking to shut down Neovasc development through litigation rather than to let the doctors decide which is right for their patients.

09:40

THE COURT: I really think that's talking about competition, not about patient care.

I will caution you not -- you've heard their concern, you've heard my view on it. The competitive part is okay. Talking about patients going to be deprived of critical care is not okay.

I'm not going to give a curative instruction on it. To the extent there's a problem, and I don't think there is, but I think it would just make it worse.

09:41

MR. SGANGA: We do have a concern that on cross-examination of our witnesses we are going to go down, spiral into this motivation for filing the lawsuit and aren't you really trying to prevent patients from getting whatever treatment --

THE COURT: So you can do the first part.

MR. FLYNN: Not the second. We hear you, your Honor. That has always been our intention.

THE COURT: Okay.

MR. SGANGA: Thank you, your Honor.

THE COURT: And I have to look at the other one.

MR. GRAVES: Your Honor, would it be possible for us to make a few remarks about the other one --

THE COURT: You can make a few remarks about it, but
09:42 I've only -- I think I got -- I think I read through page 3 and realized that it wasn't relevant to today, and I -- I wanted to be out here at 9:30, and I couldn't get through it. So I guess there's a page and a little bit of text I haven't read. Either I can read it during one of the breaks and we can talk about it later on today or you can make your comments now. It probably would be better if I finished reading it.

MR. GRAVES: Sure. Thank you, your Honor.

THE COURT: Anything else for this morning?

MR. CARSTEN: Yes, your Honor. There's one issue
09:42 we've had with some demonstratives that were shared with us. This harkens back to an issue we addressed with you on Monday.

Your Honor, CardiAQ's counsel provided to us several demonstratives, 28 demonstrates to use with Mr. Ratz, who presumably might be going on the stand today. Seventeen of those demonstratives sound directly on the inventorship

questions, more than half of them. Moreover, your Honor, we first raised this issue with you in the context of slides that Mr. Sganga may be using in his openings. Your Honor heard the argument and said, Look, guys, I'm not going to preclude you from doing this. I understand you want to get some facts in the record about inventorship, but I'm not going to let the tail start wagging the dog.

This slide is entitled, Dr. Quadri and Mr. Ratz's Design Compared to the Claimed Invention of the '964 Patent. The slides we got last night, 17 -- we can have that -- what they intend for Mr. Ratz to get up and say to the jury today is Dr. Quadri and Mr. Ratz contributed claim 1 of the '964 patent.

Your Honor, we're concerned this is now the tail beginning to wag the dog.

THE COURT: I don't think so. You're free to keep raising it, but they're trying to say that their intellectual property showed up in the '964 patent, and I think this is a fair way of doing it.

You can keep reminding me of it, you can keep raising it, but this still seems fairly dog-like to me.

MR. CARSTEN: Your Honor, your Honor, we will continue to bark.

THE COURT: Or wag, whatever.

MR. FLYNN: One last issue. The Astrid photographs, the picture of the patient surrounded by Dr. Quadri and Mr.

Ratz, that's back in the lineup today. This is opposite of what they're seeking to preclude us to do. They think every in limine is a one-way street. This goes directly to the treating of patients.

THE COURT: I think from the motions they filed this morning they think every motion you filed is a one-way street.

MR. FLYNN: We probably each -- but with respect to Astrid, we think it's not.

MS. LEA: Astrid is in the deck for rebuttal, if necessary, if they go down that road on cross-examination.

09:45

THE COURT: You're not using Astrid.

MS. LEA: In direct.

MR. FLYNN: Fair enough.

MS. LEA: Your Honor, one other issue we wanted to raise was moving exhibits into evidence.

The parties have agreed to move unobjected-to exhibits into evidence at the end of the day. After the jury leaves we can read them into the record, if that's okay with your Honor.

THE COURT: I'm concerned about if we -- let's just say he's done and gone, by the time you're ready to move them in and there's a dispute over an exhibit involving him and he's no longer here.

09:45

MS. LEA: Then it should have been raised before he took the stand or if there is some unforeseen foundational issue, then that would draw an objection. And if it doesn't,

then they'll be moved in.

THE COURT: Okay.

So what I could do is either just trust you all that this is going to run smoothly or I could, for the record, for example, when Dr. Quadri gets off the stand, say, Are there any issues with any exhibits concerning Dr. Quadri that we should address before he gets off, and give you one more quite of bite at it.

MS. LEA: That sounds reasonable, your Honor.

09:46 THE COURT: Is that all right?

MR. GRAVES: It is, your Honor. What we've discussed for each witness, there aren't objected-to exhibits the night before, some sort of foundational question will be asked to show the person does have knowledge, that will be pretty obvious with most persons on both sides of the case.

I don't think either side anticipates a huge number of objections about these things. The procedure would be at the end of the day, those documents that were shown to the person will be read into the record.

09:46 THE COURT: That's fine with me. I was thinking -- I was wondering after our discussion about the exhibits last night if we should give the jury an instruction so they don't differentiate between exhibits that are discussed and exhibits that they never hear actually moved in. But exhibits are exhibits, we've already given them that instruction so it may

not be necessary, so I leave that to you.

MR. GRAVES: I think the procedure we're talking about now would mean that every exhibit we'd be reading into the record at the end of the day would be one that the witness had actually talked about. So there won't be a disconnect between stuff that isn't going through a witness.

I think the parties are discussing potential stipulations on a block admission of certain documents, but we're not quite there yet. So this would just be things that actually went through a witness.

09:47

MS. LEA: I think we could reserve on any instruction, your Honor, and see when it comes up.

THE COURT: Okay. That's fine.

You want me to give them any -- do you want me to say anything to them about the fact that -- what I would say is that the parties are cooperating and rather than using their time to move individual exhibits in during testimony, that for the most part exhibits will be moved in at the end of the day for efficiency.

09:48

I'm just wondering -- I don't know what these people know if they don't -- I'm wondering if it's going to raise a question in their mind if we don't address it. But I leave that to you.

(Discussion off the record.)

MS. LEA: We don't have an objection to that

instruction.

MR. FLYNN: Your Honor, our only thought is that the instruction might be more meaningful when we can put it in context and we know what kind of information and what size, what body of information we're talking about. We think the instruction is appropriate.

THE COURT: So you want me to hold off on it until -- okay.

All right. Anything else for this morning?

09:48 MR. GRAVES: I think we have issues with some other exhibits for witnesses who probably aren't going to come up today, such as Dr. Hillstead who is coming up tomorrow. So we can discuss those later.

THE COURT: I'm concerned about the schedule. On Friday we can't sit before 10:00 because of this ABA thing, so we could sit from 10:00 to 2:00 which I think -- then we'd have to take a lunch break, that gives us three and a half hours of testimony on Friday.

The alternative would be if we went until 1:15 and

09:49 just took a 15-minute break. That would give us, like, a little bit less testimony but get them out of here significantly earlier. You all have a feeling how long they can sit or do you want me to leave it to them?

MR. FLYNN: Your Honor, I would leave it to the jurors to decide what's most convenient for them.

THE COURT: Let me see how we're going because I feel we absolutely need that extra half an hour. It seems crazy to have them have lunch when we could get them out of here quicker on a Friday.

Okay.

All right. I'm just going to be on and off the bench and get organized up here for the day, don't let me bother you.

(Recess taken.)

(Jury entered the courtroom.)

10:03 THE CLERK: Court is in session, please be seated.

THE COURT: Good morning everyone. Thank you for being on time. We'll get started.

We're going to continue the direct examination of Dr. Quadri.

Dr. Quadri, I remind you that you're still under oath.

Go ahead, Ms. Lea.

ARSHAD QUADRI, M.D., having previously been duly sworn by the Clerk, was further examined and testified as follows:

CONTINUED DIRECT EXAMINATION

10:03 BY MS. LEA:

Q. Good morning, Dr. Quadri.

A. Good morning.

Q. Yesterday we were talking about and you were shown a picture of the transcatheter mitral valve device?

A. Yes.

Q. Why did you want to develop a transcatheter mitral valve device?
A. The part I wanted to -- it was an unmet clinical need, and there was an opportunity for me to take that challenge on and give something new to the -- new for patients that they didn't have any other options at this point.
Q. And when did CardiAQ first start pursuing a transcatheter mitral valve device?
A. In 2008.
10:04 Q. Was it easy to develop a transcatheter mitral valve device?
A. It was extremely difficult and challenging for several reasons. And one of the reasons was the mitral anatomy itself, and the environment of the mitral valve is such that it has to be a completely different approach to it. The major challenge was that how do you put a valve there and not have it move during the cardiac cycle, during all the pressure changes. So, yes, it is -- it was a very challenging road.
Q. And what is it about the mitral anatomy that makes it
10:04 challenging?
A. There are two elements to it. First, the mitral annulus itself is a softer, much more pliable tissue than other lining of the heart.
Q. And the annulus is what?
A. Annulus is the ring that supports the fiber structure that

supports the leaflet of the mitral valve.
Q. So the ring around the mitral valve is soft?
A. Yes.
Also, the systolic pressure is going to be felt by the implant you put there, and it's just a complex scenario.
Q. The high pressure is going to be felt?
And how important is anchoring the device in a transcatheter replacement mitral valve?
A. I think -- in my opinion, that is the most important part
10:05 to figure out before you do any transcatheter valve replacement. Because you need to have a valve that stays in that position. And so the fixation of an implant in the anatomic location in the valve is critical, and that's what determines the entire success or failure of the technology.
Q. The fixation is critical?
A. Critical.
Q. Now, I'd like to go back and talk about your early mitral valve prototypes.
Who helped you make your early prototypes?
10:06 A. We basically had three -- there were three elements to the prototypes. There was the frame element, there was the delivery catheter element, and there was the tissue valve element.
So the first was the frame element. We had a vendor, and so did we for the tissue and the delivery catheter element.

Q. And who was the vendor for the tissue valve?
A. Neovasc.
Q. And how did CardiAQ select Neovasc to be its vendor for the tissue valve?
A. Neovasc had approached us, a small company. They -- we -- they basically said that there were -- had experience in tissue management, tissue valves, preparations. We had known that they had made some tissue valves, surgically implantable tissue valves, for other companies. So it looked like it was a perfect fit.
Q. And when did Neovasc approach CardiAQ to sell its tissue valves to CardiAQ?
A. That would be in the early part of 2009. My research was probably before summer of 2009.
Q. And how many employees did CardiAQ have in the summer of 2009?
A. Just one.
Q. And who was that employee?
A. Mr. Brent Ratz.
Q. Were you yourself an employee of CardiAQ?
A. No. I was a consultant to the company.
Q. And were you receiving any pay from the company at that time?
A. No, I was not.
Q. And where was CardiAQ located in the summer of 2009?

A. The official office was Mr. Ratz's residence in Boston, Winchester, Boston.
Q. Mr. Ratz's home here in Boston?
A. Yes.
Q. Now, did you ever meet with anyone from Neovasc?
A. Yes, I did.
Q. And when was that?
A. It was on June 23rd of 2009.
Q. And had Neovasc and CardiAQ entered into any agreement
10:08 prior to that meeting?
A. Yes.
Q. What type of agreement?
A. They had non-disclosure signed between the two parties.
Q. Who did you meet with from Neovasc?
A. I met -- when I visit -- I actually visited them at the facility. I met Mr. McPherson, Mr. Randy Lane, Kulwant Lall was the valve technician, and also I had a brief meeting with the CEO.
Q. When you say you met with them at their facility, where
10:09 was that?
A. In Vancouver.
Q. Vancouver, Canada?
A. Yes.
Q. Now, how long was your meeting with the people at Neovasc?
A. It was over two hours.

Q. And who did you meet with for two hours?
A. The majority of the time was spent with Mr. Lane, Randy Lane, and we basically spent the time discussing what I wanted him to do for us. I did have a short meeting with -- short tour with Mr. McPherson and with the CEO, but these were very short meetings.
Q. And what did you tell -- sorry. What did you and Mr. Lane discuss regarding your mitral valve?
A. We had -- the discussion ranged in three different areas.
10:10 We discussed the anatomy of the mitral valve. We discussed the tissue valve construct of the mitral valve. The majority of the discussion was around the tissue, how do we make that, and also the fixation mechanism of mitral prosthesis in that mitral location.

The discussion ranged quite a lot about the tissue valve construct. My concern was that every valve that I had seen at that point -- and also my belief was that even Neovasc did not have -- I didn't know if they had any experience with mounting a valve onto a frame, a stent frame, which was
10:11 entirely different from the surgical frames. So I had a pattern of a valve that I wanted them to construct called origami, take a flat piece of paper and you cut it into shapes and if you fold it around, that will become a valve. The idea there was how can we -- the main discussion was how do we mount pericardial tissue onto a collapsible stent that can go from

small to large and not have any disruption of sutures that holds it there or not have any disruption of the valve tissue itself. So we talked, we talked about that. And then the discussion also ranged into --

Q. Let me stop you there for just one minute.

So focusing on your origami tissue valve idea, did you bring with you a tool to help make that tissue valve?

A. Yes.

Q. And what type of tool was that?

10:11 A. We had designed a mandrel, which is a 3-D print, a printed structure.

The theory was that to have a constant production of the same valve every time and take the humor errors out of it, if you have a mandrel, you wrap the pericardium around it and just follow the curves of -- the bends in that mandrel, you will have a single valve every time. So I took that with me to demonstrate that to them.

Q. I'd like to show you Trial Exhibit 328.

MS. LEA: May I approach the witness, your Honor?

10:12 THE COURT: You may.

BY MS. LEA:

Q. Do you recognize Exhibit 328?

A. Yes. This is the mandrel.

Q. That's the assembly mandrel?

A. Yes.

Q. Is it the mandrel that you provided to Neovasc?
A. Yes.
Q. And did you have that mandrel 3-D printed?
A. Yes.
MS. LEA: Your Honor, may I publish the mandrel to the jury, pass it to the jury?
THE COURT: Any objection?
MR. FLYNN: No objection.
THE COURT: Go ahead.
10:13 (Exhibit passed to the jury.)
(Pause.)
BY MS. LEA:
Q. Now, you also said you discussed the fixation mechanism --
A. Yes.
Q. -- with Mr. Lane?
A. We did.
Q. And what did you talk about the fixation mechanism?
A. I had -- the impetus to go into this field was that I had a mechanism of fixing a prosthesis to an anatomic location and
10:14 that was with shortening and prongs that came off of the shortening, and it was a type of stent that I had developed that was an invention of mine. So that's what I felt that -- the discussion was, How are we going to fix it? So I said I have this method, so we went over that whole concept of pinching the leaflets and the annulus so the valve could be

stationed in that location.
Q. Did you talk about your earlier frame designs with Neovasc?
A. That we did.
Q. And did you have a frame with you?
A. We showed them a frame, yes.
Q. And which one was it?
A. It was the Rev. B.
Q. Did you also talk about the differences between the
10:15 transcatheter mitral valve technology and the transcatheter aortic valve technology?
A. Yes.
Q. What was that discussion?
A. That discussion ranged -- was focused on fixation again. Subcutaneous technology, you rely on the calcium that is deposited in the valve, and that is why the stenosis happens. So what we do is we put a stent in there. We make the stent larger by a balloon, and that -- the calcium around and the mechanism of force that is generated by taking a small stent
10:15 and making it into a large one by increasing the diameter, it just stays.
But that's not the case with a mitral, and mitral has to have an active mechanism of fixation. That was the whole point of me being confident that the technology that I had developed was going to be taken forward into the mitral.

Q. So the technology that was used in transcatheter aortic valves would not work for transcatheter mitral valves?
A. No.
MR. GRAVES: Objection, leading.
THE COURT: Reask the question, please.
BY MS. LEA:
Q. Doctor, would the technology that was used in a transcatheter aortic valve work for a transcatheter mitral valve?
10:16 A. No, it would not.
Q. Now, what were the first devices that Neovasc assembled for CardiAQ?
A. The Rev. C of the Generation 1, and then we had some Rev. D assembled by them, and Rev. E assembled.
Q. And did you bring a large model of your Rev. C prototype today?
A. Yes.
Q. Is this that model?
A. That is the one.
10:17 Q. And is this a fair and accurate representation of Rev. C?
A. That would be correct.
MS. LEA: May I approach the witness, your Honor?
THE COURT: You may.
BY MS. LEA:
Q. Can you please use the Rev. C model to describe the Rev. C

device to the jury and explain what Neovasc did in regards to that device?

A. So this is the mitral valve implant. So let's go from outside to inside.

So, first of all, let's discuss the way -- the layout of the stent frame is, which is this metallic.

So there are two sets of projections coming out. This would be on the top and that would be the atrial side, and this would be on the bottom. There is a skirt that is surrounding the entire bottom of the -- of the -- of this implant.

Q. You're calling that fabric a skirt?

A. This is a skirt.

So if you can notice, all of the angles are covered on this skirt. And this part is going to stay inside the ventricle.

Q. The lower chamber?

A. The lower chamber, the pumping chamber of the heart.

So let's go -- on the inside, this yellow material is basically the plastic that is protecting the pericardial tissue, and this is a triatrial valve.

Q. What does "pericardial" mean, doctor?

A. It's a covering of the heart with a membrane, that the heart is enclosed in a sack, and that is called the pericardium.

Q. And where did the pericardial tissue come from that

Neovasc put into the frame?
A. This pericardium was a porcine pericardium. So usually that's what we use for heart valves.
Q. It's animal tissue?
A. It's animal tissue. It's taken from pigs, and it is very well-known. And also bovine pericardium is also known, you may be familiar with, that comes from a cow, and these are used in heart valve constructions.
So they use the tissue to make this valve. It's
10:19 triatrial valve, symmetrical to open and close with systole and diastole.
Q. With the pumping of the heart?
A. With the pumping of the heart.
So this would be the way this is going to sit. And every systole, the leaflet is going to shut, with every diastole, the leaflet is going to open with contraction.
Another thing to differentiate is the diameter of this. So it's like a cylinder at this point. This is like -- this is about 30 millimeters in diameter. So this is the
10:20 geometry of the implant that we had in the first sample from them.
Q. Thank you, Dr. Quadri.
Now, what part of the Rev. C device did Neovasc assemble?
A. They assembled the entire tissue part, and they assembled

the fabric skirt part. So this was -- so we gave them the frame, and they assembled it.

Q. Now, once you received the assembled Rev. C prototypes from Neovasc, what did you do?

A. We went to -- we applied for some animal testing in University of Minneapolis, and by their protocol and approvals from their IACUC committees, they permitted us to go have these devices tested in sheep. So that was our first animal experimentation that we did in Minneapolis.

10:21 Q. And so for this animal study you submitted a written protocol?

A. Yes.

Q. And that was approved -- I'm sorry, what was the name of the approving board?

A. It's called IACUC.

Q. Was there a veterinarian involved?

A. Yes. It's Institutional Committee for Care of Animals, and so that reviews the protocol very careful, sees that the animal is going to be of value to the development of

10:21 technology. So they evaluate all of that, and then they give you permission to do the animal work. So they allowed us to do some sheep, use some sheep for this.

Q. And what was the goal of the early animal studies?

A. The goal was to demonstrate that the concept of fixation of this valve really works, and that was the first thing that

me and my partner, Mr. Ratz -- basically our focus was we need to have an implant that really works before we go forward in anything, and so that's what we decided to do.

Q. And what was the fixation technique for the Rev. C prototype with the fabric skirt?

A. It was pinching the leaflet and the ledge of the annulus, pinches the leaflet.

Q. So pinching or clamping the leaflet to the annulus?

A. That would be correct.

10:22 Q. And was this anchoring approach successful?

A. No, it was not successful. The implant was rejected, dislodged immediately.

I just want to also say the implant was doing -- using excellent surgical techniques with the animal taking -- just you would do an open heart surgery valve replacement. So surgically implanted, because the goal was to just study the fixation of the device.

Q. You didn't sew any stitches or sutures around this valve?

A. No sutures were used.

10:23 Q. Could you tell why the pinching was not working?

A. Because the tissue -- there's not enough tissue to grab hold of things, of the implant. The pressures are very high. And one thing that I really hadn't figured before going was that the part that I am trying to placate, pinch with this implant, pinch with this implant is the going to the mitral

valve leaflets. So the mitral valve leaflet is like that, I'm pinching around it. When you think about it, every time a systole occurred, that leaflet got pulled.

Q. Every time a contraction occurred?

A. Every time a contraction occurred that leaflet got pulled, and once it got pulled, it shifted the device into the left atrium. So those were the issues that we were facing at that point.

Q. And what did you do when you realized the pinching approach was not working?

A. So I had my engineer, Mr. Ratz, with me. So we discussed that we need to make some changes and continue the experimentation. So what we did was to divide the fabric between this and free up the anchors. So what that did was the anchors became independent elements of the implant and also they could expand. This was restraining, so they could not expand out. And so, well, if you do those changes, let's see what we -- how we can make this work.

Q. When you say "divide," what does that mean?

A. Just cutting.

Q. So you cut through the fabric skirt between the anchors?

A. Yes.

Q. Did freeing the anchors help?

A. Yes, it did. We had success, and we went back and did more animals and for the first time we had some success. You

could see it was stable all the time. It was very encouraging.
Q. Now, did anyone record your study once you cut through the Rev. C skirt and free the anchors?
A. Yes.
Q. Who did?
A. We were a small company, it was me and Mr. Ratz, and Mr. Ratz was doing all the recording and engineering and putting it all together. Both of us were working together on that.
10:25 Q. Did he record it by video?
A. Yes.
Q. I'd like to show you a portion of the video today as Trial Exhibit Number 1442.
(Played recording.)
A. So if you can see, these ones have cuts on them. This is intact, this is the intact skirt.
Q. Meaning it hasn't been cut?
A. Hasn't been cut. And this one has been cut. You can see that. It's not clear, but you can see the fraying of the
10:26 edges, the anchors are freed up. So cut these, and they became independent anchors.
Q. So the record is clear, Trial Exhibit Number 1442, which revision is shown in that video?
A. This is Rev. C.
Q. We have a Rev. C with an uncut skirt and a Rev. C with a

cut skirt?
A. Yes.
Q. After these August 2009 animal studies, what did you do next?
A. The next -- the next thing we did was we came back home, and we basically modified the stent. There were two things that was happening here. Number one also was -- there was a lot of breakage that was happening to the portion of this, this portion of the stent, because there was a lot of contraction
10:27 and pressure on it. So what I did was take an extra layer of stent from top, let's say here, and we transposed it down there to make it more robust. And we did that, and we twisted some wires and fixed that very well. And you freed the entire edges up. And then we decided to go back to get some more permission and resubmit the protocol with the changes, and we were allowed to go back and do the experiment another time.
Q. I'm sorry, one more question on the video.
When was that video taken? What month and year?
A. That was in July of -- August of 2009.
10:28 Q. Is it August 2009?
A. If memory serves me right, probably. I may get my dates wrong, but it was in that time frame.
Q. You took the video at the animal study?
A. At the study.
Q. In August of 2009?

A. Yes.
Q. Okay.
So focusing on the modified Rev. C, that Rev. C did not have a skirt?
A. That Rev. C did not have a skirt.
Q. You had taken the skirt off.
I'd like to show you Trial Exhibit 1374.
MS. LEA: May I approach the witness, your Honor?
THE COURT: You may.
10:29 BY MS. LEA:
Q. Doctor, do you recognize Trial Exhibit 1364?
A. Yes.
Q. What is it?
A. It's a modified Rev. C frame.
Q. Does it have a skirt on it?
A. No.
Q. And what type of material is the frame in?
A. It's formaldehyde.
Q. Formaldehyde?
10:29 A. Yes.
Q. So we'll keep it in the jar.
MS. LEA: Your Honor, may I publish Exhibit 1374 to the jury?
THE COURT: Any objection?
MR. FLYNN: No, your Honor.

THE COURT: Go ahead.

(Exhibit published to the jury.)

BY MS. LEA:

Q. Okay.

I believe you were telling me about implanting the modified Rev. C?

A. Yes.

Q. And when was this animal study conducted?

A. It was September.

10:30 Q. September 2009?

A. Yes.

Q. And was this implant successful?

A. Yes.

This was -- this was the implant. This was the animal experiment that convinced me and Mr. Ratz that we could go forward with our technology. It was the moment, aha moment, that we had.

Q. And what did you observe as far as the anchoring?

A. It worked. The implant was stable in position. It did

10:30 not migrate. We had good hemodynamics. We could gather that data, the animal was alive at the end of the experimentation.

Q. And what did you observe as far as the anchors?

A. Then we -- according to protocol, we euthanized the animal and we studied the implant, how it was fixed, and it demonstrated what we had done when implanting at this time.

Since I had no more cover, when I put the implant in, I made sure that I would take the leaflets and go over the anchors. So this is open heart surgery, the heart is still, it doesn't move. So when we put the implant in, I had to lift the leaflet and put it over the anchors. And we did that, and basically it worked.

So what happened -- what we did was to demonstrate that if you go -- if the anchors go within the chords and go and touch the annulus and the leaflet falls between the anchor and the stent, the main body of the stent, that would be the key to a stable fixation.

Q. So capturing the leaflet is the key to fixation?

A. Yes. Capturing the leaflet, going behind. I want you to understand that. Just capturing the leaflet -- if the chords are all cut, you can still catch the leaflets. That would be half of the story. That would not really work well. So you have to have the chords intact so you can go around it and then capture the leaflets.

Q. So you're going between the chords, around the leaflet --

A. Yes.

Q. -- capturing it --

A. Yes.

Q. -- and anchoring on the annulus?

A. Yes.

Q. Did anyone record the September 2009 animal study?

A. Yes.
Q. Who did?
A. Mr. Ratz.
Q. I'd like to play Trial Exhibit 1445.
(Played recording.)
Q. Let's start that again, Trial Exhibit 1445, with audio.
Let me first ask, did you recognize Trial Exhibit 1445?
A. Yes.
10:33 Q. What was it?
A. This is the animal after euthanasia and we had taken the implant, the heart out, expanded the heart.
Q. And why did you do that?
A. To study, to see exactly what the fixation was like.
Q. So let's watch the video again, this time with audio.
(Played recording.)
Q. So whose voices were those on the video?
A. That was mine and Mr. Ratz's voice.
Q. And what did you mean when you said it went under the
10:35 leaflet?
A. Well, that's -- the point is that we went under the leaflet between the chords. And so the leaflet fell between the implant and the anchors.
Q. So are you still pinching or clamping the annulus now?
A. No. We are engaging the annulus, but they're not pinching

or clamping there.
Q. And what did you learn from the September 2009 animal study?
A. It was a great moment, aha moment, as I describe it, and we said we can go forward and do more studies. And we looked at other options of improving the -- the stent and the implant so we could continue the study forward.
Q. And did you further modify your device after the September 2009 animal studies?
10:35 A. Yeah, that was very encouraging result, and we modified based on the potential anatomies that we were going to deal with in animals. So we made changes in the implant, and basically we're getting ready to do more animal work.
Q. And what was the next revision that you implanted in an animal?
A. The next revision in an animal was Rev. E.
Q. I'd like to show you Trial Exhibit 1007.
(Pause.)
Q. Do you recognize Trial Exhibit 1007?
10:36 A. Yes.
Q. What is it?
A. This is Rev. E.
Q. Is that a complete Rev. E with both the frame and the tissue valve?
A. This is both the Rev. E with frame and tissue valve.

Q. And who put that tissue valve on Rev. E?
A. Neovasc.
MS. LEA: Your Honor, may I publish that to the jury?
THE COURT: Any objection?
MR. FLYNN: No objection.
THE COURT: You may.
(Exhibit published to the jury.)
BY MS. LEA:
Q. And what are some of the differences between Rev. C and Rev. E?
A. The basic concept is the same. I just want to point out a few things here.
The diameter from here to here is different than the diameter from here to here. That is basically because we want to put in a 40 millimeter annulus, the size of the animal's mitral valve. And then these are the anchors, basically the ventricular anchors and atrial anchors. And the pericardial valve is sewn onto this. So those are the changes that I could point out.
Q. Now, did you share the features of Rev. E with Mr. Lane?
A. Yes, I shared the features with Mr. Ratz who was in communication with Mr. Lane and me.
Q. Did you have any phone calls with Mr. Lane about Rev. E?
A. I personally didn't have any phone calls with Mr. Lane at this point, but later, in December of 2009, we had -- so what

had happened here is we've changed the dimensions of these -- this implant. This used to be a cylinder, and now it's a cone. So we had a conference call with Mr. Lane, we were making this change, that we needed to modify the leaflet, the leaflet geometry, because now it's -- from a cylinder it's easy to cut the leaflets out of as three pieces in the cylinder rather than the cone. So basically a bell-bottom design was discussed, and we had a good, healthy discussion at a conference call.

Q. And so you told Mr. Lane you were changing to a two-level design?

10:39

A. Yes.

Q. Now, did you perform any animal studies with the Rev. E devices that Neovasc assembled?

A. Yes.

Q. When were these studies performed?

A. They were performed in 2010. We did study in March of 2010.

Q. And where was the March 2010 animal study performed?

A. At this point we had found a nice animal lab facility here in Massachusetts, in Boston called CBSET, and that's where we did the animal work.

10:39

Q. And who performed the March 2010 animal study?

A. With the help of the veterinarian scientists.

Q. And did you submit protocol for this study itself?

A. Protocol were submitted and reasons for the study were

submitted and they approved it.
Q. And what type of animals did you use in the March 2010 study?
A. At this point we had gone to -- we had gone to pigs.
Q. And why did you use pigs for this animal study?
A. We didn't need sheep because pigs have a very similar anatomy to the human heart. In fact, pig valves are used in humans.
So -- and also, the -- the main reason for the sheep
10:40 is being castigation study, which is not the focus of our study. So it was just easy, procurable, and it fit the purpose really well.
Q. And do the pigs have chordae tendineae similar to humans?
A. Yes, similar anatomy to human beings.
Q. And the pigs have leaflets similar to humans?
A. Yes.
Q. And do the pigs have an annulus similar to humans?
A. Yes.
Q. And do the pigs have fibrous trigones similar to human
10:41 fibrous trigones?
A. Yes.
Q. I'd like to show Trial Exhibit 1395, and this is a series of 8 photographs.
Dr. Quadri, do you recognize Trial Exhibit 1395?
A. Yes, I do.

Q. And what is it?
A. This is an implant in a porcine heart, pig heart. You can see these anchors, the ventricle anchors, of the leaflets.
Q. Before we talk about the heart, are these photos from the March 2010 animal study?
A. Yes.
Q. Please tell me what you see in the photo?
A. The ventricle had been opened. First of all, this is the necropsy picture of the porcine heart. And here is the opening
10:42 into the left ventricle, and they're trying to see from the lift-up to see exactly how the engagement of these anchors has occurred. So here we can clearly see that these anchors have gone over. This whitish portion is the leaflet of the animal, and this yellowish portion is the native artery.

So we can see that quite clearly in that picture.
Q. Let's go to page 3, please.
A. Here shows the same. I want to explain this a little bit.

You're looking, again, from the ventricle and the valve like that.
10:43 So what we see here is inside here will go from inside out. This is the prosthetic valve, the leaflets. Outside here you see the anchors that wrap around these chords and basically go around.

So you can say this is between the chords. This one is between this chord and that chord, and you can just see.

What we don't see here clearly is the annul contact, but you can imagine that up north of that is the annulus. So systolic pressure is going to put it there.

Q. Does this photo show the anchors going between the chordae tendineae?

A. Yes, I just explained that.

Q. And does this photo show the anchors capturing the leaflet?

A. Yes.

10:43 Q. If we could go to page 5, please.

And what is shown on this photo on page 5?

A. This is a great demonstration of capture here, of going around the leaflet, and then the tips of these anchors are touching the annulus, this whitish portion. And this would be -- since white and glistening, that would be the trigonal area.

Q. So did these anchors go between the chords?

A. I will have to presume they do, but I really can't -- the chords are not seen here, but to get there, because the chords

10:44 are now plastered onto the implant, but to get there, they'd have to because we see a little bit of the chords here. But it's not as clear as the last picture.

Q. The last picture and this picture, page 3 and page 5, they're from the same heart?

A. Yes.

Q. The same implant.

And did the anchors in this photo -- we've already talked about the anchors capturing the leaflets. The anchors engaged on the annulus?

A. Yes.

Q. And what part of the annulus did the anchors anchor on?

A. This is the trigone.

Q. The fibrous trigone?

A. Yes.

10:45 Q. Now, were these March 2010 animal studies the only studies you performed with the Rev. E devices?

A. No. This was not, just to say this, we followed this up, of course, with studies, same lab.

MS. LEA: And you can take that photo down.

Q. So when did you perform the next animal studies with Rev. E?

A. In April of 2010.

Q. Now, in April of 2010 did you surgically implant the Rev. E into a pig heart?

10:45 A. No. In April we did the whole procedure percutaneously. So we had the lab load it into --

Q. Let me just ask.

So you had a living pig?

A. Yes. So the pig was living, it was not on bypass. The heart was beating, fully anesthetized, and so that was asleep

and so the access so the heart was gained from the groin.

Now, the pig's groin -- the veins to pigs are really small, so we had to do some maneuvers to dilate them up, for that a small incision was necessary, very small. And then after that, we inserted the entire line through that vein to the heart.

Q. So you performed a transcatheter procedure implanting the Rev. E in a living pig?

A. Correct.

10:46 Q. And which type of transcatheter procedure did you do?

A. Transseptal transcatheter, transfemoral transcatheter, transcatheter implantation.

Q. So let's go over that.

"Transfemoral," what does that mean?

A. It's through the femoral vein in the groin.

Q. So you make a small incision in the groin?

A. We made a small incision. We were just forced to because, as I explained, the vessel is small in an animal, and you can see their legs are little, so they don't have a big vein. And

10:47 then you dilate it up so that we can get this device in. And then we go up into the heart and then cross over to the left side of the heart across the septum.

Q. The septum is the wall --

A. The wall that separates the left atrium from the right atrium. And position it in the mitral annulus and deployed it.

Q. Now, Doctor, are you aware of anyone else who has successfully implanted a prosthetic mitral valve into an animal transfemorally?

A. No. That was -- that was -- this was another breakthrough in our technology. Nobody had ever done it. We were the first ones to demonstrate. People talked about it, but never demonstrated in an animal. So we were pretty excited. This was like the eureka moment. So we are going forward with our technology, the fixation works, and it was great. Nobody had done it then, and even now I haven't seen anybody come forward and do it.

10:48

Q. No one has reported today that they have done it.

Now, I'd like to show you Trial Exhibit 2634.

What is this photo?

A. So this is the necropsy of the same animal that it had been implanted in, and basically shows really clearly how the anchors have gone between the chords and resting on the annulus. And this is the trigone valve. This is the aorta that had been cut this way, otherwise it just rests on that portion. And this is another between the chords and touching the trigone. It's just through this leaflet, which is basically covering it over, and I can see all these anchors are between the chords. And what I've done here is to divide the muscles and sort of take back the muscle and dunk it into the body of the valve so we can study the engagement. So this was

10:49

the image.
Q. This is a photo of the animal heart with the valve implanted in it and you're studying the fixation.
A. Yes.
Q. Now, after the Rev. E prototypes, did CardiAQ order any other set of prototypes from Neovasc?
A. No. After that we basically severed our business contact with Neovasc by about a couple of weeks after that.
Q. And did CardiAQ continue to conduct animal studies in Boston throughout 2010?
10:50
A. Yes.
Q. Now, after the animal studies in Boston, what did you do next as far as the animal studies go?
A. After that, we basically -- after this -- after this study --
Q. So you just testified that you had conducted more animal studies in Boston, and then did there come a time when you changed locations for your animal studies?
A. Correct. The location for animal studies -- after this
10:50
study was very key moment, and there was a surgeon that -- interventional cardiologist approached us after our meeting, Dr. Lars Sondergaard, and he offered his animal lab. We had to do more studies. So we started doing animal studies in Denmark, in Copenhagen and at their facility. So we did quite a few animals in that facility, just to streamline, the

delivery catheter, the whole developmental process.
Q. And did you attend those studies?
A. Yes.
Q. So you flew to Denmark?
A. Every month. I was going to Denmark month every two weeks.
Q. And about how many animals did you and Dr. Sondergaard do in Denmark?
A. By the time we were ready to go and do a case, we were about 60 animals or so in.
Q. And was CardiAQ continuing to improve the device during this time?
A. Yes.
Q. Now, I'd like to show a demonstrative, PDX 2.116.
And what is shown in this demonstrative?
A. This demonstrative shows the evolution and changes in the valve of Gen. 1. So we go -- we started, we discussed D, then we go E, and we go all the way to Rev. J. These are all based on engineering and what would engineering permit and what would be the width and diameter and detailed tissue designs as well.
Q. Now, are you able to identify the changes between the Gen 1 devices?
A. Yes. So we can -- basically you see there are a lot of dimensional changes here that I can see.
The change from here to here, these are basically the

same, but I can't tell them here from the pictures.
Q. Let me just ask you, Doctor. Did the anchoring concepts behind the Gen 1 devices change over time?
A. No.
Q. Now, there was a change, right, from Rev. C to Rev. D?
A. Yes.
Q. And then were there any changes to the anchoring concept after Rev. D?
A. No.
10:53 Q. So the concept of going between the chords and around the leaflets and anchoring on the annulus, that remained?
A. That remained. That has not changed.
Q. From Rev. D on?
A. On, yes.
Q. Now, at some point did CardiAQ have the opportunity to allow its device to be implanted into a human?
A. Yes.
Q. And when was that?
A. That would be June of 2012, we did our first human
10:53 implantation in Copenhagen.
Q. And Copenhagen is where?
A. Denmark.
Q. And Denmark is in Europe?
A. Yes.
Q. And who was to be the implanting doctor for that?

A. The team of doctors there, Dr. Lars Sondergaard, the head of the team, the cardiologist.
Q. And that's the doctor you mentioned that you performed the animal studies with?
A. Yes.
Q. Now, what type of case was this? Was this -- had you attained regulatory approval for the device?
A. No. We were in the process of doing regulatory approval, but this was a compassionate patient that didn't have any other
10:54 option.
Q. What does that mean, to be a "compassionate patient"?
A. There is no options, and he is basically going -- the patient is going to die within six months to a year, a miserable quality of life. So that was the patient. And Dr. Sondergaard, while we were going and trying to arrange some studies with them, had asked us -- requested CardiAQ to give them the device so they can have -- this patient made the request and we discussed it and we said we should try and help.
Q. And so this patient had severe mitral regurgitation?
10:55 A. Severe mitral regurgitation, heart failure. He was not having any quality of life, he couldn't do anything, and he was just in bad shape.
Q. How old was he?
A. He was 87 years old.
Q. Now, were you personally involved in the first

implantation in that human patient?
A. Yes, I was.
Q. So you flew to Denmark?
A. I was in Denmark. We went there before we transitioned from human to animals. We had a lot of discussion with the team there, talked to the doctor's team. These consisted of cardiologists and their surgeons and their specialists and their anesthesiologists and everybody, and perfusionists, sat together and we had a plan to go ahead and do it as safely as
10:56 possible for the patient.
I presented some slides to them and basically explained to them how it should be done, and I felt comfortable with the team would be able to perform the operation, procedure.
Q. And was the CardiAQ device successfully implanted in the patient?
A. It was successfully implanted, transfemorally, transseptally, successfully implanted the device.
Q. Transfemorally, so it came in from the groin?
10:56 A. From the groin we implanted it. Once we implanted the device, we took the mitral valve liters down from four plus to one.
Q. So you improved the mitral regurgitation from level four --
A. -- down to one. And that's the grading of mitral

regurgitation. You can say a mild, moderate, severe or you say one plus, two plus, three plus, four.
Q. So you took it from severe to mild?
A. Yes.
Q. And did the patient regain consciousness after the procedure?
A. He did wake up, and he did wake up and had a meaningful interaction with his family.
Q. And how was the patient's ultimate outcome?
10:57 A. It was unfortunate. We lost the patient in 24 to 36 hours. The night of surgery he was looking really good, and we were all very encouraged. He took all of the parameters to create the human into shock in the middle of the night, and they -- there were options to intervene and save, but there was discussion with the family, and the family said they didn't want any other heroic measures on him, so he passed.
Q. And what was the cause of his death?
A. It was an acute systemic inflammatory ischemic response.
Q. And was the cause of death in any way related to the
10:58 heart?
A. No.
Q. And was it in any way related to the CardiAQ device?
MR. GRAVES: Objection, speculation.
THE COURT: Can you lay a better foundation, please?
MS. LEA: Sure.

BY MS. LEA:
Q. After the patient passed away, was an autopsy performed?
A. Yes.
Q. And did you attend that autopsy?
A. I did.
Q. Who else attended the autopsy?
A. Dr. Sondergaard, their pathologist, and chief of cardiology was also in, and personnel.
Q. And what was the determination made at the autopsy?
10:58 MR. GRAVES: Same objection, your Honor.
THE COURT: Foundation.
MS. LEA: Present for the autopsy.
THE COURT: Is he aware of the results of the autopsy?
BY MS. LEA:
Q. Are you aware of the results from the autopsy, Doctor?
A. Yes.
Q. And did the autopsy report any type of -- that the death was in any way due to CardiAQ's device?
A. No. This was issued by the hospital records, and they
10:59 determined the cause of death was non-implant related, non-valve related, due to, as I said, the cause of death was -- was acute systemic ischemic response and leading to bowel ischemia, leading to irreversible shock.
Q. So I don't know if I know what all that means, but it sounds like -- is there any way to relate it to the heart?

A. No.
Q. Now, after the patient passed away, were you able to verify that the implant had deployed correctly in the patient?
A. Yes.
Q. And how did you do that?
A. We looked at the -- the -- after the patient passed way?
Q. Yes.
A. So we looked at the autopsy and that demonstrated the implant was in the intended location and it was stable and
11:00 fixation was great.
Q. And in the autopsy, could you see the anchors on the device?
A. Yes.
Q. And how -- where were the anchors in the heart, the ventricular anchors?
A. There were anchors around the chords trapping, engaging the annulus. The leaflet was captured and anchors also had contact with the annulus and the trigone.
Q. So the anchors went between the chordae tendineae?
11:00 A. Yes.
Q. And the anchors went around the leaflets?
A. Yes.
Q. And captured them?
A. Yes.
Q. And the anchors anchored on the annulus?

A. Yes.
Q. Including the fibrous trigones?
A. Yes.
Q. Now, did you later make changes to the CardiAQ device?
A. We did.
Q. And if I could bring up demonstrative 2.17, please.
And what changes did you make to the CardiAQ device?
A. The -- what we did was -- so here it bothered me that there was this portion of the implant, we talked with the
11:01 engineers, there was a lot of expansion there and it was sort of abutting the myocardium. So we took that distance in, so we sort of made it -- we made it slanted in, tapered. We used to call it a pumpkin shape. We did that. And the anchors, we basically just flattened them out a little bit, and made them such that we could cover them in fabric.
Q. So you put fabric over the anchors?
A. Yes, these exposed anchors were covered in fabric.
Q. Was that a skirt like we saw with Rev. C?
A. No.
11:01 Q. What was it like?
A. Each leg had its own -- own sleeve.
Q. More like pants?
A. More like pants.
And also we put -- what we did was to use specialized material for that, yes.

Q. Now, did the Gen 2 device have the same anchoring approach as Gen 1?
A. Yes.
Q. And what approach is that?
A. The anchors go behind the -- between the chords, behind the leaflets, and contact the annulus, circumferentially on the annulus.
Q. Now, did you ever implant the Gen 2 device -- or did CardiAQ ever implant the Gen 2 device in a human patient?
11:02 A. Yes.
Q. And when was the first one?
A. The first one we did in the summer of 2014, and we did that case in Denmark, again at the same hospital with -- all of the same physicians that were involved in the first participated in the second one. The first Gen 2, that would be the first Gen 2.
Q. And was this another compassionate use case?
A. Yes. These patients that we did in Europe were all compassionate cases.
11:03 Q. And how old was this patient?
A. At that point she was 88 years old. In fact, we just sent her a birthday cake for her 90th birthday.
Q. She's still alive today?
A. Yes. She's alive and well, she's 90 years old.
Q. And she's had the device implanted in her for two years

now?
A. Yes.
MR. GRAVES: Your Honor, may we approach?
THE COURT: Yes.
Members of the jury, we're going to have a quick conversation over here. If you want to stand up, stretch, move around a little bit, if you want to take advantage of the break.
(At sidebar on the record.)
11:04 THE COURT: Before you speak, they can talk about the 88 or 90-year-old. It was the pictures that we can't elicit testimony about it.
Did you have anything other than that?
MR. GRAVES: I think that what they're doing right now is opening the door to the very things we're not supposed to be talking about. It didn't have anything to do with merits issues. It was just a gratuitous description that this person is still doing well two years later with the intention of telling the jury that everything is perfectly well with this,
11:04 and I thought that's what we weren't supposed to be doing.
THE COURT: How many patients have gotten -- how many live patients have gotten the implant?
MS. LEA: That are still alive today?
THE COURT: No, how many altogether?
MS. LEA: Sixteen.

THE COURT: How many of them are alive today?

MS. LEA: Six.

THE COURT: If you want to elicit that 10 of them are dead, that's fine.

MR. GRAVES: I think we should have a limiting on this kind of stuff going forward, because I thought that was the ground rules --

THE COURT: The ground rules, I don't want it to be about patient outcomes. But there's a certain amount of narrative that is necessary to sort of explain to them what's happened. She did elicit that, it was gratuitous, having an instruction makes it worse. I don't think this will be much beyond the scope of my ruling.

I'm not going to give you too much latitude on any individual patient circumstances.

To the extent that you elicited some of them are alive, you can elicited some of them are dead.

MS. LEA: And we had just done that. We had elicited one that died.

MR. FLYNN: I only suggest that given the feature of the exam, to keep things moving we've not objected to.

The idea that that was inadvertent is at least subject to some skepticism, particularly in light of the pictures of this woman and the picture of the birthday cake.

THE COURT: It's hard to know. He's very excited

about the fact that he's got an 88-year-old that's alive.

So but I don't want this to be too much about patient outcomes, but to the extent it's part of the overall startup development of the device, it's inevitable to a certain amount.

MR. GRAVES: Thank you, your Honor.

THE COURT: We can talk about it further when the jury is gone.

MR. GRAVES: Thank you.

(End of discussion at sidebar.)

11:06 BY MS. LEA:

Q. Dr. Quadri, have there been any additional implants of the CardiAQ device?

A. Yes.

Q. And has CardiAQ had any occasion to perform any cases in the United States?

A. We have.

Q. And how is it that CardiAQ is able to perform cases in the United States?

A. We applied to the FDA and got an early feasibility trial

11:07 approved. They gave us permission to do 20 cases in the U.S., 10 transseptal, that would be femoral approach, groin approach; and 10 transapical.

Q. And transapical is --

A. Is through the left chest through a small incision.

Q. Now, Dr. Quadri, you've described CardiAQ's clinical

success. Has CardiAQ had business success as well?
A. Yes.
Q. And what happened last year?
A. Well, CardiAQ, it's a success story. It's an American success story we're getting at. The world's most reputable and biggest heart valve company bought CardiAQ outright for $400 million.
Q. What's the name of that company?
A. Edwards Lifesciences.
11:08 Q. When you say Edwards purchased CardiAQ for $400 million, where did that money go? Did it go to you?
A. Not all of it. The money went to all the investors that had put faith and money to it, and over the years they have invested a lot of money into it. So all of those particularly invested money gain from it.
Q. And just in general, who were some of the investors?
A. We had very great reputation, surgeons, the world's best surgeons and doctors that invested in the company. But what really comes to mind is that my staff who was working with me
11:08 in my hospital. They wanted to invest, and we talked about it, but they -- I told them that, you know, the regulations are such that I can't take your money, because the cutoff was too much. So they said --
Q. The minimum amount of investment was too much?
A. The minimum amount was at least $100,000. So they -- so

walk in, one of the members said, Hey, it would be nice to have Rose, her two-year-old at that time, send her to college, so Dr. Q., can we do something? So that sparked an idea. I said why don't you guys get together and form an LLC, a small company, pool in the money and invest, and they did. Actually, they did -- they invested twice, and 25 -- 10 to 25 thousand in the range each one of them pitched in. And I tell you, they're very happy people today.

Q. And what was the name of that LLC?

11:09 A. Rose LLC.

Q. And who is Rose?

A. Rose is that little two-year-old girl of my -- my office staff.

So, I mean, that's the heartwarming part of this, really that.

Q. Doctor, did you receive any of the money?

A. Yes, I did.

Q. And how much did you receive?

A. Total take for me would be about $20 million.

11:10 Q. And why did you receive that much?

A. For my efforts for the last decade in developing this technology. I had invested a lot of my own money in it earlier on, over $300,000. And also over the years I had gain in equity because of the work I was doing because it was me and Mr. Ratz for a long time, and then it was all the time, I was

working with the company all the time.

So all of the founders' shares and the options and gathered up and that's how -- that's how much my take would be.

Q. And what did Edwards' purchase of CardiAQ mean to you?

A. It's a great success for me. It was phenomenal. Barring the money -- this company bought my technology. Now I see a future for the valve. I see that some day the patients that are basically not being helped today will get what they need, a transcatheter mitral valve, a transseptal mitral valve replacement. That's huge for me, barring -- the money is good obviously, benefitted from that. I couldn't be happier because this is just a phenomenal achievement for my team, and also people trusted me, and I could deliver. So all that coming to me successfully.

Q. Now, Doctor, are you aware that the defendant, Neovasc, claims you disclosed your trade secrets and confidential information to the public through presentations and patent publications?

A. No.

Q. Are you aware that they make that claim?

A. They probably do, yes.

Q. Now, did you ever share the physical prototypes of Rev. C, D, or E with the public?

A. No.

Q. Who did you share the Rev. C, D, and E physical prototypes

with?
A. Obviously Mr. Ratz, we shared it with Neovasc.
Q. Did you ever share the development history of Rev. C, D, and E with the public?
A. No.
Q. Who did you share the development history of Rev. C, D, and E with?
A. With Neovasc.
Q. I'd like to show Trial Exhibit 615, please.
11:12 Do you recognize Exhibit 615?
A. Yes.
Q. What is it?
A. This is a presentation I made to the TCT, transcatheter therapy. This comes from a panel in Washington, D.C.
Q. And if we can quickly flip through and you can just tell us real general quickly what you presented at this conference.
I'm sorry, what months was this conference, TCT?
A. It was in the fall, September of 2010.
Q. September of 2010.
11:13 A. So these were my disclosures. This is an important slide. You have to disclose, that's what I was doing for the company at that point.
If you have the next slide, please.
This here shows -- I was trying to impress upon my colleagues, my peers that this is the problem with mitral

regurgitation. It's such a dramatic, bad disease that here is they all die at the end of five years from the start. You see how the heart failure progresses. There's no fix for this. That was the whole impetus for me going after this disease process.

So I made that point. You know, this is great discussion we had.

And here we go, this is another area that we wanted to concentrate on, 9.3 percent to 75 percent of patients is 11:14 increasing at that rate. If you look at the data, it's really alarming how many patients are turned back with mitral regurgitation and cannot be helped. It's over 60 percent of patients that turn up in the office with mitral regurgitation will be turned back without any therapy. Medical therapy, but nothing else.

Q. Can we go to the next slide, please?

A. This is what happens. If you fix it, as I spoke before, fewer than 20 percent recover, 13 percent operative mortality, 77 survive at one year, and 55 at five years. So you see how 11:15 dramatic that drop is. So 50 percent of patients die.

Q. If we can go to the next slide, please.

A. So I was trying to show that we developed a transcatheter mitral valve implantation technique, it's a new approach.

Q. And the next slide please, page 6.

A. So this what was claim was provide chordal sparing mitral

valve repair with a competent, bioprosthetic mitral valve. "Chordal sparing" means we don't use divide the chords, they're not divided, they're maintained, the vital anatomy is maintained.

Eliminates the risk associated with cardiopulmonary in the heart/lung machine.

Q. That's the open heart surgery?

A. Open heart surgery. And those are elements of that procedure.

11:15 High-risk patients, those who are not candidates for surgery, could receive definitive therapy. You give them a competent value or at least reduce it to one plus.

Q. If we could go to the next slide.

And generally what is shown on this slide?

A. So this is like -- it should have secure anchoring, optimal hemodynamics, avoid systolic anterior motion. It's a technical term in medicine, cardiology that we use. It is avoid left ventricle outflow tract obstruction, preserve mitral valve apparatus, eliminate MR.

11:16 Q. And these are your must-have guidelines?

A. These are the goals we set out to basically establish.

And then we have to have a catheter delivery system, deploy the mitral annulus; and then, of course, we have to have a loading system. So this is a general overview of what we were trying to do at that point.

Q. Let's go to slide 8, please.
A. And this is what we showed. As this demonstrative shows, catheter comes up, goes across the septum, there you go, and releases these anchors, and they will go between the chords and they will affix to it.
Q. Now, which revision is shown in this drawing on slide 8?
A. This will be Revision B.
Q. Revision B?
A. Yes.
11:17 Q. So the one before C?
A. Yes.
Q. Before D?
A. You can see the pinching going on here.
Q. So this uses the old method of anchoring, the pinching?
A. Yes.
The main purpose of this demonstration was, okay, this is the route and this is what we are trying to do.
Q. And why are you still showing your old method of anchoring in September of 2010?
11:17 A. Well, we're certainly not going to disclose our new method. That was a very fair question asked in the meeting, how does it fix, how does it fix. This was one of the major questions in my presentation, and I told them, Well, that's the secret I cannot share with you. So this question was asked several times, several locations. People are amazed, why is it

not moving. We never discussed that part.

Q. If we could go to page 9, please.

Now, what's shown on page 9?

A. This here is the Rev. E design of the valve, prosthetic valve with these anchors. And on here is an animation, how it works.

Even this animation, if you play it, it's just foreshortening, shows the clamping, the foreshortening.

Q. Did you tell the audience how the Rev. E device anchored?

11:18 A. No, not in any detail at all. It was just that it anchors, foreshortening happens.

This is what this video shows, that it comes together like that, and that was enough for the big crowd to understand. Because this was not a technology meeting, I was not discussing technology here.

Q. Did you disclose going between the chords and around the leaflets and anchoring and the annulus?

A. No.

Q. And if we could go to the next slide, please.

11:19 And what's shown in this slide?

A. This one here is the video that showed the entire procedure. Coming up and going across, so this catheter comes up and across the left side and goes into the left ventricle. And basically, you know, this is just showing the early part of the procedure, on the video that would be very interesting.

So that's -- this is the video. I call -- this is the video that -- I call it the inception. So this is where it all shows how it works.

Q. But now when you say that, Doctor, does it show the anchoring method?

A. It shows the anchors come out and affix, but it doesn't show the method.

Q. Can you see the chordae tendineae?

A. No.

11:20 Q. Can you see the leaflets?

A. No.

Q. Now just quickly go through, if we could show the next slides, slide 11 and slide 12 and 13 and 14 and 15 and 16 and 17 and 18 and 19.

Now, did any of those slides show the method of anchoring?

A. No.

Q. How long did you present for at TCT in September of 2010?

A. This would be a max ten minutes, seven- to ten-minute

11:20 rotation.

Q. And you didn't hand out any prototypes --

A. No.

Q. -- at the presentation?

A. No, in fact, we always tell the meetings not to publish, just the presentation, slides back. So they didn't even have

this material to put in their deck.
Q. Now, if we could take that down, please.
Now, did the U.S. Patent Office grant CardiAQ any patents on its TMVI devices and methods?
A. Yes.
Q. How many patents have you received?
A. Currently about nine.
Q. And are you a named inventor on all of CardiAQ's patents related to TMVI?
11:21 A. Yes.
Q. And did CardiAQ file a patent describing the way the Rev. D and E devices were anchoring in the mitral valve?
A. Yes.
Q. If you could please show Trial Exhibit 2173.
Is this the patent that discloses --
A. This is the patent that discloses it.
Q. Now, let's look at when this patent was filed, if we can. Actually bring up the provisional filing date.
And do you see the entry number 60 there?
11:22 A. Yes.
Q. What is that?
A. September 23, 2010.
Q. Is that when you first filed your anchoring method with the Patent Office?
A. That would be the official application date, yes.

Q. Was your patent application public on that date?
A. No.
Q. And when did your patent on that method publish?
A. About 18 months later.
Q. Eighteen months later?
A. Yes.
Q. I think it actually shows the date on the front, if we can show the publication date. Is that it right there? I'm sorry, it was up.
11:22 Read number 65.
A. Yes, publication date.
Q. And what's that date?
A. March 29, 2012.
Q. Let's read into the record the patent number, if we can.
A. U.S. Patent 8,652,203.
Q. If we could turn to column 16, line 17.
A. So this just describes the anchors capturing the mitral leaflet and going around the mitral leaflet.
Q. And I believe we can highlight that. If we could
11:23 highlight the first sentence there. What does that sentence say?
A. Replacing the heart valve can be deployed at a patient native mitral valve annulus with reference to Fig. 8.
Q. Let's skip down. I believe we had some more highlighted text.

A. Yes. With the downstream side of the native mitral valve annulus. In this motion, preferably the downstream anchors will engage and capture the native leaflets. So that's -- the native leaflets are engaged and captured, and then can be deployed to allow expansion of the replacement valve.
Q. If we could highlight the sentence that starts at line 23.
A. That's -- describes the chordae tendineae, the anchors going between the chordae tendineae. So we describe how we are going to achieve this.
11:24 Q. And so it says the heart valve to be partially deployed so that the downstream portion of the replacement heart valve can be allowed to self-expand, thus urging the downstream anchor between the chordae tendineae and radially outward of the native mitral valve leaflets.
A. That's correct.
Q. Was that your invention, of going between the chords, around the leaflets, and engaging in?
A. Yes.
Q. Now, are CardiAQ's inventions disclosed in its patents?
11:25 A. The -- when patent issues, but not when they're provisional applications.
Q. Now, did CardiAQ disclose its development history in its patents?
A. No.
Q. Are you aware of defendant Neovasc's TMVI program?

A. Yes.
Q. How did you find out that Neovasc was developing a transcatheter mitral valve device?
A. This information came to us through -- I was informed by one of my colleagues, my neighbor, actually. And he says, Have you heard about the TMVI valve? This is a competition that's coming up, did you know about it? Because my neighbor was very involved, he's a good friend of mine. I said, No, I haven't heard about it. So that evening, me and Mr. Ratz, as per
11:26 routine, we usually discuss the company business a lot. So I brought up this, you know, that I heard this from this Mr. Such and Such. So we talked about it. He hadn't really heard about it either. So we said why don't we just look it up. And we were on the phone and we just went to USPTO.gov, the Patent Office.
Q. The Patent Office website?
A. Yeah, website and typed in "Tiara," boom. Tiara valve, Neovasc, and the inventor was Mr. Randy Lane.
Q. And when was this?
11:26 A. This would be around December of -- later on in early two thousand -- actually, it will be end of 2010, early 2011.
Q. So could it have been December 2011?
A. Yes.
Q. All right.
And did you say that Randy Lane was named as the

inventor on the Neovasc patent?
A. Yes.
Q. And that's the man you had met with at Neovasc?
A. Yes.
Q. How did you react to seeing this information?
A. I was furious. I mean, we were like shocked and furious and say, What is this? We have not -- we never expected this off a vendor that was basically trusted. We trusted all our technology, we gave them all the information. They never told us. And so it was -- it was not -- it was not a good day for me. We were very upset about the whole thing.
Q. Did you find Neovasc's actions to be unfair?
A. Very unfair. It was sort of betrayal. You know, you trust somebody with all this information, and they just go ahead and make their own device and compete directly with you. I don't mind competition, competition is great, but, you know, not this -- stealing. So that was -- that was pretty bad.
Q. Now, do you know if the patent application you saw published in December 2011 has issued into a patent?
A. Yes.
Q. It has; is that right?
A. Yes.
Q. If we could show Trial Exhibit 565.
A. Yes. So this is -- this is the Neovasc patent.
Q. And it's U.S. Patent 8,579,964?

A. That is correct.
Q. And can we see the original filing date for the original application in number 60 there?
So when was Neovasc's first application filed on -- if we could highlight the first one at the bottom.
A. Filed on May 5.
Q. May 5, 2010?
A. Yes.
Q. And when did CardiAQ stop working with Neovasc?
11:29 A. That would be about a couple of weeks before this.
Q. Maybe even a week before it?
A. Yes.
Q. Now, do you believe that you should be named as an inventor on the '964 patent?
A. Yes.
Q. If we could turn to claim 1.
A. Yes. So these claims, as you read all the way down, it's like you go in around the leaflets, the engage the trigone, which is a portion of the annulus, you capture the leaflet.
11:29 That's all described in this patent.
Q. I'd like to start at the top, Dr. Quadri. If you can go paragraph by paragraph and what your contributions were to this invention.
A. So providing a prosthetic -- comprises an anchor having an atrial skirt, an annular region, ventricular skirt and

plurality of valve leaflets. The ventricular skirt comprises of first trigonal anchoring tab disposed on an anterior portion of the ventricular skirt, wherein the anchor has a collapsed configuration for delivery to the heart and an expanded configuration for anchoring with the heart. This is the description of the left ventricle anchor.

Q. That's a description of your devices that you showed Neovasc?

A. Yes. And then positioning the prosthetic valve in the 11:30 patient's heart, expanding at atrial skirt radially outward so as to lie over a superior surface of the patient's native mitral valve.

Q. Let me ask you about the highlighted part. Is that something you contributed?

A. Yes.

Q. And if we could go down to the next paragraph, "radially"?

A. Radially expanding the annular region of the anchor to conform with and to engage the native mitral valve annulus. That's engaging the mitral annulus, that's what we do.

11:31 Q. And the next paragraph.

A. Anchoring the first trigonal tab against a first fibrous trigone on a first side of an anterior leaflet of the native mitral valve, such that the anterior leaflet and the adjacent chordae tendineae are captured between trigonal anchoring tab and an anterior surface of the anchor.

So that physically describes that you go behind the leaflet and engage, capture the leaflet, go up and touch the annulus, in being in contact with the annulus, and it also goes for the adjacent chords, which means the chords could also be of the posterior leaflet. "Adjacent" means next to each other. So there could be anterior chords, posterior chords. So there could be both. So this is what that is.

Q. Okay.

So when it talks about anchoring the first trigonal anchoring tab, that's one anchor, right?

A. That is one anchor.

Q. And that's like your ventricular anchor?

A. That is like my ventricular anchor going to the annulus, and that's key, is the annulus, it has -- it goes to the annulus, and it gets there, it just, you know, by capturing the leaflet.

Q. And then the next paragraph?

A. And then radially expanding the ventricular skirt, thereby displacing the native mitral valve radially. That's like when you expand the mitral valve, it's now is going to get pushed out to make room for the new valve. So that's what that says.

Q. And this is the -- the highlighted portions of the method were the portions that your Rev. E device performed?

A. Yes.

Q. Now, if we could turn to claim 14.

Did you contribute to claim 14 as well?
A. Yes.
So now if I can describe the way this patent is applied for, the way it's working is like -- so describe one tab that goes against one, then they describe another tab, a second that's opposite to the first tab that is in claim 13. That goes opposite the first tab. So now we've got two tabs going around the leaflet, capturing the leaflet, and getting up on the top. But that's not going to work, because it's too -- 11:34
it's like two legs to a stool, it's not going to stand, you need a third leg, at least three legs for a stool to stand. So to get the third leg, they describe this third anchor, which is as it's read here --
Q. Dr. Quadri, I just want to verify. We talked about claim 1 that required one anchor?
A. Yes.
Q. Now we're talking about another claim that's adding a second anchor?
A. Yes.
Q. Where would this anchor anchor on the annulus? 11:34
A. 14 would be in the posterior part.
Q. And the "posterior part" means where?
A. Posterior part of the annulus. And this --
Q. "Posterior" means the back of the annulus?
A. The back, yes.

Q. The softer portion in the back?
A. Yes.
Q. Not the front where the trigones are.
A. No.
Q. That was in claim 1?
A. Right.
Q. And is there anything else included in this patent that you shared with Neovasc?
A. So this is the third anchor, this describes the whole anchoring method.
11:35
The other thing that I shared in this patent is the approach, the transseptal approach that goes --
Q. If we could go to claim 3.
A. Transseptally delivering the prosthetic valve from the right atrium to the left.
Q. And that's the same as your transfemoral approach?
A. Yes.
Q. To your knowledge, has Neovasc even performed the transseptal approach?
11:35
A. No.
Q. But they put it in their patent?
A. Yes.
Q. If we could see Fig. 23 A.
And what is shown in Fig. 23 A?
A. That's a replica we've been discussing goes from here.

This is the vein. The vein all the way going across into the right atrium and then going across the septum into the mitral valve.

Q. So this is the method that you use that goes through the groin, up the femoral vein, across the wall of the heart, and down into the mitral valve?

A. Yes.

Q. And that's not what Neovasc does today, right?

A. No.

11:36 Q. But they put it in their patent?

A. Yes.

Q. Now, how did it make you feel to see your contributions in Neovasc's patent?

A. I was extremely angry and basically felt that, you know, very, very cheated and betrayed, that how -- there has to be a discussion about this. They had to talk to me, me and Mr. Ratz, before they go forward and make a claims that we have -- we basically taught them. We experimentally proved them, we gave them the information, we gave them the history,

11:37 and one week later, they come up with a publication -- an application that's completely stolen from our technology. It was not a good day. I felt very betrayed and angry at that point.

MS. LEA: Thank you, Dr. Quadri. I have no further questions at this time.

THE COURT: While they're switching places, why doesn't everybody stand up, stretch, move around a little bit, if you want to.

(Discussion off the record.)

CROSS-EXAMINATION

BY MR. GRAVES:

Q. Good morning, Dr. Quadri.

A. Good morning.

Q. Let's start with Exhibit 2634, which was already marked this morning.

Dr. Quadri, if I understand you correctly, this is a photograph from an animal study in April of 2010, and it shows one of your devices, in your words, going behind the leaflets in through the chordae; is that correct?

A. That is correct.

Q. And you testified this morning in response to this photograph this was huge, correct?

A. Yes.

Q. You told us that this was the sort of thing that your company didn't publish or make public at industry conferences; is that correct?

A. That is not entirely correct. We published the picture, that was shown.

Q. This picture was published in May 2010, one month later, at a conference called Euro PCR, correct?

A. I'm not aware of that. I wasn't at that meeting.
Q. You're aware that Dr. Carlos Ruiz at Euro PCR in May 2010 gave a presentation that included information from your company, CardiAQ, correct?
A. Yes.
Q. And your company gave him this photograph for materials for the conference presentation, correct?
A. I did not hand the presentation to him. I would have to check, but that may -- you may be right. I just didn't go
11:38 through the presentation that was sent to him.
Q. And you're aware that there's more than one conference in 2010 where this very photograph, this is huge photograph, was published at an industry conference, correct?
A. That is correct.
Q. So when you testified earlier that you didn't go and tell people and your company didn't go and tell people at conferences about this anchoring fixation method, that wasn't entirely correct, was it?
A. It was entirely correct in my description, it just showed
11:39 a picture of how the engagement happens, but it doesn't describe to a medical community that it was presented to, it just gives the evidence that valve in a stable location and that cannot be displaced. That was the message going out.
Q. We can look at this picture and see anchors, in your words, behind the leaflets, correct?

A. That is correct.
Q. You mentioned you spoke to Mr. Randy Lane of Neovasc around June 23rd of the year 2009; is that right?
A. That is correct.
Q. Now, when you met Mr. Lane, you didn't say, Hey, Mr. Lane give me a list of any devices you've ever seen before that have anchoring structures that go behind the leaflets? You didn't do that, did you, sir?
A. Well, that was not entirely in the question, no, but that
11:40 was presumed, that all the disclosures would have had to have happened.
Q. You didn't ask him for a list of devices he knew about before he met you that went behind the leaflet, correct?
A. Correct.
Q. Now, you testified --
A. Excuse me, mitral.
Q. Dr. Quadri, you testified about your device this morning. So I'm going to ask you some further questions about it.
In your CardiAQ device, there are 12 anchors on the
11:40 bottom ventricular side of the device, correct?
A. That is correct.
Q. In fact, there is a complete circle of 12 anchors on the bottom ventricular side of the device, correct?
A. That is correct.
Q. There is also a complete circle of 12 anchors around the

circumference of the top or atrial side of the device; is that correct?

A. That is right.

Q. Total of 24 anchors, correct?

A. Yes.

Q. And if we compare the circle, that circumference, to the face of a clock, your 12 anchors are spread around the circumference like numbers on a clock 12 midnight to 12 noon, correct?

11:41 A. Right.

Q. Those anchors are each about 30 degrees apart from each other around that circle, correct?

A. That is correct.

Q. During any procedure in which your device has been implanted in a human, no doctor performing that procedure has ever tried to put a particular anchor on that clock face on a particular part of the mitral annulus, correct?

A. No, we don't do that.

Q. And it doesn't matter, because all the anchors are the

11:41 same in your device, correct?

A. They are.

Q. You don't have a clocking that you need to do in anchoring your device, correct?

A. Correct.

Q. By "clocking," you understand that I mean picking a

specific number on the clock, like 6:00, and intentionally sticking a specific anchor on 6:00, correct?

A. Yes.

Q. All right.

Now, if we look at your device, any particular anchor can go into any particular place around the mitral annulus because they're all the same, correct?

A. That is correct.

Q. CardiAQ didn't give any of the 12 anchors on the bottom ventricular side of its device special individual names, correct?

A. No.

Q. You never named any of the 12 anchors on the bottom ventricular side of your device trigonal tab, correct?

A. No.

Q. You never named any of the 12 anchors on the bottom ventricular side of your device posterior tab, correct?

A. Correct.

Q. You didn't give your anchors special names that correspond to prenamed anchoring spots, correct?

A. Correct.

Q. And you didn't give names to your anchors that way because you don't have a unique preplanned anchoring spot for each particular anchor, correct?

A. We do.

Q. You don't actually take anchors and deliberately place them in preplanned locations that are unique to each anchor, correct?
A. Correct.
Actually, that would not be correct. We do. We place them on the annulus.
Q. And anyplace around the annulus is good enough for you, correct?
A. Correct.
11:43 Q. It's like that old TV game, the Wheel of Fortune. We can spin the wheel, wherever it lands is wherever it lands, and that's okay, but as long as it's on annulus, correct?
A. The Wheel of Fortune -- it will land with one, the whole wheel. You have to imagine the whole in time, the numbers, but they can be 12:00, 3:00, 4:00 or the wheel can end at some other number. So it's not a good analogy, sir.
Q. Let's try another one.
In a baseball game, you understand the person who's called the third base coach, they need to stand next to third
11:44 base?
A. All right.
Q. Further questions about intentional anchor placement. Until this lawsuit was filed you never heard the term "fibrous trigones" used internally at CardiAQ, correct?
A. You don't do justice to what I do for a living.

MR. GRAVES: Your Honor.
A. I am a cardiac surgeon.
MR. GRAVES: Your Honor, I would like to play Volume I of Dr. Quadri's transcript under 32(a)(2), pages 287-2 to 287-5, and we will bring that transcript up for your review.
THE COURT: 287-2 to --
MR. GRAVES: 287-5.
THE COURT: Volume I.
MR. GRAVES: Volume I, yes, your Honor.
11:45 THE COURT: Objection?
MS. LEA: Just for completeness, your Honor, we'd like to add 6 through 12.
MR. GRAVES: That's not the question, your Honor. The question is covered by 287-2 to 287-5.
MS. LEA: It's the same question, your Honor.
THE COURT: You want to add --
(Pause.)
THE COURT: All right. You can play 287-2 to 287-5. I think the question is basically the same, and the most
11:46 efficient way to do this would be to play through 12. Are you set up to do that?
MR. GRAVES: I don't know if we are, your Honor.
MS. LEA: Then they can read it, your Honor.
MR. GRAVES: If it's the same question, I'd ask it word for word, I think should we should just play the one what

we've got.

MS. LEA: It gives the witness' full answer.

MR. GRAVES: They can do redirect later.

THE COURT: I understand the point, they can do redirect later, but it seems, for the sake of efficiency, to give it now given the similarity of the two questions.

So we can discuss how we're going to handle this later, but for the time being let's play or read 2 through 12, please.

11:47 (Pause.)

THE COURT: If you're only set up for 2 through 5, we can either read it or play it right after lunch break. I don't mean to put the technology people on the spot.

MR. GRAVES: Your Honor, do you mind if one of my colleagues simply reads it so we can move on?

THE COURT: Yes, that's fine.

MR. GRAVES: Mr. Baskin, can you read the pages, please?

MR. BASKIN: "Q. Until this lawsuit was filed had you

11:47 ever heard the term 'fibrous trigones' used internally at CVT?

"A. No.

"Q. Is the term 'fibrous trigone' -- leaving aside any conversations you've had with lawyers -- used internally at CVT today?

"A. Not particularly. We consider that clarified

before. Fibrous trigone to me is part of the annulus, and we talk about the annulus all the time."

BY MR. GRAVES:

Q. Dr. Quadri, CardiAQ has never instructed a physician who will be implanting the CardiAQ device to specifically target the fibrous trigones with a specific anchor, correct?

A. Yes.

Q. And when you did your first in-human implantation, which you spoke about this morning, and in deciding that was a

11:48 success, you didn't consider whether one or more of the 12 bottom ventricular anchors had attached to a fibrous trigone in the patient's heart, correct?

A. Excuse me, please repeat that question. You said "bottom anchors."

Q. When you did your first human implantation and deciding that that was a success, you didn't consider whether one or more of the 12 ventricular anchors had attached to a fibrous trigone in a patient's heart, correct?

A. Yes, that is correct.

11:49 Q. And in your communications within CardiAQ and your investor group at Organ Net in connection with that implantation, you never discussed whether one or more of the 12 ventricular anchors had attached to a fibrous trigone in a patient's heart, correct?

A. To the annulus.

Q. You didn't discuss whether the 12 ventricular anchors had attached to a fibrous trigone in a patient's heart, correct?
A. No. But to the trigone annulus, because a trigone is part of the fibrous or the annulus.
Q. You didn't discuss whether they attached to the fibrous trigones, correct?
A. Correct.
Q. For before this lawsuit started you never told anyone that your Revision C of your device was intended to target or hit upon a fibrous trigone, correct?
A. Yes.
Q. "Yes" means correct, right?
A. Correct.
Q. Before this lawsuit started you personally never told anyone that Revision D of your device was intended to land upon fibrous trigone, right?
A. Correct.
Q. Before this lawsuit started you never told anyone that Revision E of your device was intended to land upon a fibrous trigone, correct?
A. That is correct.
Q. Because you didn't tell anybody that Revisions C through E were intended to anchor on a fibrous trigone, that includes Neovasc, too, as well, correct?
A. That would -- yes.

Q. For example, when you visited Neovasc in Vancouver in June of 2009, you didn't mention the fibrous trigones, correct?
A. That is not entirely true. We talked about the mitral anatomy. And if I'm talking about mitral anatomy, we are talking about the fibrous trigones.
Q. You didn't mention the fibrous trigones, did you?
A. I have no recollection.
MR. GRAVES: Your Honor, I would like to play Volume I, this time from 188-20 to 23.
11:51 THE COURT: 188-20 to 23.
(Pause.)
THE COURT: Go ahead.
(Played recording.)
BY MR. GRAVES:
Q. And the answer is the same for the posterior shelf. You never told anybody at Neovasc that Revisions C through E of your device were intended to have one designated anchor always land on the posterior shelf, correct?
A. That's correct.
11:51 Q. Your Revisions C through E were not rotationally oriented so that each anchor needed to land in a unique preselected location every time, correct?
A. That's correct.
Q. In fact, you've said that you think Neovasc Tiara would be a better device if it didn't have rotational alignment to place

specific anchors to hit certain points, correct?
A. I don't remember that.
MR. GRAVES: Your Honor, I'd like to play Dr. Quadri's deposition, Volume I, pages 150-3 to 151-7.
THE COURT: I'm sorry, 153 --
MR. GRAVES: 150, line 3 to 151, line 7.
THE COURT: Any objection?
MS. LEA: Just a moment, your Honor.
(Pause.)
11:53 MS. LEA: Your Honor, if we could go through 151-11.
MR. GRAVES: That's okay with me, your Honor, if we've got it.
THE COURT: That's fine.
MS. LEA: And I'd like to also add the first question in this series, page 149-16. So going from 149-16 through 151-11.
MR. GRAVES: We disagree with that, your Honor.
(Discussion off the record.)
MR. GRAVES: Your Honor, we don't agree with that.
11:54 That's an unrelated question.
MS. LEA: It is related, your Honor.
THE COURT: Hold on.
(Pause.)
THE COURT: No, not going to allow that at this point. You can get it on redirect if you want.

150-3 through 151-11.

(Played recording.)

MR. BASKIN: Your Honor, we'd read the next lines into the record.

THE COURT: That's fine.

MR. BASKIN: "Q. So looking at the device, do you have an idea in mind on how it could be improved?

"A. Just adapt the CardiAQ valve technology fully, and you will be there."

11:56 BY MR. GRAVES:

Q. Dr. Quadri, just to be clear, you think that Neovasc's device would be improved if it just adopted your technology instead of doing clocking and rotational alignment and having a D shape, correct?

A. That's the conversation that went on there. And they did adopt some of it, so --

Q. All right.

Well, you add more anchors to it as well, not just the through anchors that Tiara has on the ventricular side,

11:57 correct?

A. Bottom ventricle left side.

Q. You think it needs more anchors, don't you?

A. The device itself?

Q. Yes.

A. Yeah, I have 12 anchors with my device.

Q. And you think Tiara's three are not enough, correct?
A. As I said, three-legged stool is stable, you just have to balance them correctly.
MR. GRAVES: You know, I think we're going to be here for a while Dr. Quadri, because I want to play Volume I now, 151-16 to 17.
(Pause.)
MS. LEA: Your Honor, the transcript's not inconsistent with his testimony.
11:58 THE COURT: I agree.
BY MR. GRAVES:
Q. Well, let's be clear here, sir.
You think the Neovasc device would be better if it had the same number of anchors as your device, correct?
A. Correct.
Q. Let's look in your binder, sir, in front of you, Trial Exhibit 5024.
You see that in your binder, Dr. Quadri?
(Pause.)
11:58 A. Yes, I see.
Q. You have 5024 in front of you, sir?
A. Yes.
Q. You see it on the screen in front of you?
A. I see it.
Q. This is a report, a summary, that you were involved in at

your company that was created around March 25 of 2016, correct?
A. Yes.
Q. This was something that you were personally involved with, correct?
A. That summary? I was there at that point.
Q. And this was a summary following an implantation procedure of your device, correct?
A. That is correct.
Q. If we look down the bottom of this March 25, 2016 document, the very bottom of the document on the first page, it says, "position of anchors relative to the trigones." Do you see that?
A. Yes.
Q. Before this lawsuit started CardiAQ never purported to measure or document the position of its ventricular anchors relative to trigones, correct?
A. That is correct.
Q. There are no words even in this document from March 2016 stating that CardiAQ intentionally places each specific anchor in a unique and exclusive preplanned anchoring location, correct?
A. Yes, that is correct.
Q. You talked about the leaflets, and I want to start with some nomenclature.
In a situation like this one, there are fabric

leaflets as well as natural leaflets, correct? Leaflets that are made that are artificial that go into a valve; is that right?

A. I am not aware of any fabric leaflets.

Q. There's tissue that's made to put into the valve assembly for a prototype, correct? And you can sometimes refer to those as leaflets, correct?

A. You can call them, but they really -- are you talking about just rough prototype to get the geometry right? You can cut it out of paper, yes, but it's not a leaflet.

Q. There's natural leaflets that are inside the valve, correct?

A. They're natural, yes.

Q. And there's also artificial leaflets, correct?

A. Prosthetic leaflets with tissue, tissue leaflets.

Q. Yes. So when you talked about prosthetic leaflets earlier when you were discussing a phone call with Neovasc in December 2009, prosthetic leaflets are distinct from the leaflets you were talking about when we were talking about going behind the natural leaflets, correct?

A. The prosthetic leaflets used in a prosthetic valve are different than the native leaflet, yes.

THE COURT: Mr. Carsten (sic.), are you coming to a good stopping point for lunch?

MR. GRAVES: Let's do it now.

THE COURT: Are you sure? I don't want to disrupt your train of thought.

We're going to take a lunch break, 45 minutes if you can. If that turns out to be too long or too short, we'll adjust, just try 45 minutes. Just remember everybody eats in the same cafeteria. Talk to each other, try not to interact with any of these lawyers, I know there's a lot of them. So you all stay way from them, too.

We'll see you back in about 45 minutes.

12:02 (Jury left the courtroom.)

THE COURT: Sorry, the court reporter just told me I called you by the wrong name. My apologies, there's a lot of you.

MR. GRAVES: That's okay, your Honor.

Can we get an order sequestering Dr. Quadri during lunch because we're still in the middle of questioning?

THE COURT: You want them not to be able to eat with him or not to be able to talk to him about his testimony?

MR. GRAVES: The latter, your Honor.

12:03 THE COURT: That's fine.

So no conversation about his testimony.

Their point is you finished direct, you're on cross-examination now. Your cross-examination should not be influenced by any conversations with anybody else. So you may have lunch with them and you may discuss the quality of the

food, but you may not discuss this case or your testimony in the case. Do you understand?

THE WITNESS: Yes, ma'am.

THE COURT: If you think that will be too difficult, you can go and each lunch by yourself.

THE WITNESS: No, I will not discuss it.

THE COURT: He says he'd rather eat with you.

I don't know, reasonable minds can differ on that. But he can do as he chooses.

12:03 We'll see everyone back about quarter of.

MS. LEA: Yes.

(Court recessed at 12:03 p.m.)

(Resumed, 12:45 p.m.)

MR. GRAVES: Your Honor, there's an issue I'd like to discuss before the jury comes in.

THE COURT: Talk fast.

MR. GRAVES: It has to do with FRCP 32(a)(2) versus 32(a)(6), during the colloquy. The question is whether the opposing party is able to suggest additional designations on

12:46 impeachment clips. And we checked all this during the break. And if it were a deposition playing to put into evidence under (a)(6), you can certainly do that, but under (a)(2) for impeachment, you can't. So I don't believe we should continue with the additional requests for further video. It's either impeaching or it's not.

THE COURT: So in some of the questions where you've asked him -- and I can't -- I didn't realize you were going to raise this so I can't put it together exactly now. You were asking to play deposition testimony where I don't think it's strict impeachment, right? You didn't ask the same question, or he gave an answer that was equivocal but not contradictory. And in those circumstances, just as a matter of efficiency, I would rather have them play it all, but if you want to hold to a strict impeachment standard, I'll give you that, but if they object because the response from the stand is not inconsistent with the transcript, I'm going to interpret that strictly, too.

MR. FLYNN: My only point on that is I think the standard is inconsistent, so it doesn't need to be contradictory. Equivocal suffices.

THE COURT: Well, I take your point. But on that first one where I gave them the extra, I felt that that was -- the answer wasn't exactly inconsistent, and, you know, it made sense. The other one I actually would have sustained the objection, but you all agreed to have it played. I would have sustained that one. I think I did sustain it on the third one, right?

MR. GRAVES: I don't believe so. Yes, Your Honor. Thank you.

THE COURT: So give me -- what are the two rule numbers again? I'll go back and look at them.

MR. GRAVES: FRCP 32(a)(2) versus FRCP 32(a)(6).

THE COURT: For efficiency, I don't know. I just --

MR. FLYNN: May I say half a sentence on efficiency?

THE COURT: Yes.

MR. FLYNN: I really do think we'll save much more time to leave that kind of stuff for redirect if they choose, provided the clips are truly impeachment. If they pass that standard, I think the railroad will run more smoothly if we just get to play them.

12:48 THE COURT: That's what I would expect someone sitting in the chair that you're sitting in to say.

MR. FLYNN: Thank you, Your Honor.

THE COURT: Someone very wise once told me that where you stand depends on where you sit.

(Jury enters.)

THE COURT: So at the end of the day, I hope -- or during the break, I hope you guys will take a few minutes to talk to Karen about whether you think the lunch break is too long, not long enough. Some jurors like a little less time,

12:50 some like more time. Obviously, a two-hour lunch would extend the length of the trial, so it's sort of a balance.

The other thing is that I know everybody is doing their best, but there's a lot of people involved in this trial. I'm concerned about sort of the congestion in the cafeteria and the elevators, and there may more be commingling than I'm

really comfortable with. So I spoke to the clerk of the court yesterday. And during jury deliberations it's routine that the court will bring lunch up to the room and you don't have to leave the room. They've given me permission to have lunch sent up every day and you can eat in that room.

And I'm going to leave it to you. The upside is you get a free lunch every day, and you may not feel rushed. The downside is I also don't want you to feel like prisoners in that room and we're not letting you out for a whole day. So another thing to discuss amongst yourselves during the break. Maybe if we're bringing you lunch, the 45 minutes is okay. Whatever you guys come to is fine with me. The idea is to keep you comfortable.

You also get -- I'm sure you figured this out. You get a snack a day. When we're sitting full days I usually do the snack in the afternoon. I do it that way because at least me, I need a little more of a break in the afternoon than in the morning when I start a little fresher. But all of that can be adjusted. Like maybe if you're getting lunch -- I don't know. I'm trying to keep the breaks during the day to an hour, 45 minutes for lunch and a 15-minute break, but however you guys decide you want to break that up, we have some flexibility in that. So again, we're working our way up to the bigger decisions, but there's a smaller one -- two smaller ones for you to start with.

You can resume your cross.

MR. GRAVES: Thank you, Your Honor.

BY MR. GRAVES:

Q. Dr. Quadri, you spoke this morning about going behind the leaflets. And what that means is the anchors on your device hold the leaflets up toward the annulus by gathering them or plicating them, to use a more technical term, correct?

A. The gathering and plication is a result of that movement, yes.

12:53 Q. And you've also referred to that, Dr. Quadri, as folding, correct?

A. Yes.

Q. You've described that as folding like a curtain or like an accordion, correct?

A. Bottom up, yes, accordion.

Q. And because the leaflets in your design are folded like a curtain or like an accordion, they're not left unfolded, correct?

A. They're not left unfolded.

12:53 MR. GRAVES: Bill, if we can show Exhibit 2634, which was used in the direct testimony again this morning.

Q. Dr. Quadri, if we focus again on this photograph, the white around the edges shows us the folding of the leaflets; is that correct?

A. The white around the edges are more chords than leaflets.

Q. So the chords are the string-like tissue; is that correct?
A. Right.
Q. We also see some folded leaflets in there, in that photograph, correct?
A. Yes, between the chords.
Q. Just for the record, to be clear, this photograph was not shown to Neovasc to your knowledge, correct?
A. To my knowledge, no.
Q. And to be even more clear, Neovasc didn't attend any of
12:54 the animal studies, the animal implantations that you described this morning, correct?
A. They did not attend.
Q. And the same is true for the human implantations, the human surgeries you've also described this morning. Neovasc wasn't there also for those either, correct?
A. No.
Q. Now, you testified this morning about both of the devices, your device and Neovasc's. To begin with your device, your early development for your device was primarily for the heart's
12:55 aortic valve up until about August of 2008, correct?
A. Yes.
Q. And it was around August 2008 that you and Mr. Ratz decided to switch your focus to a mitral device, correct?
A. Yes.
Q. The aortic version of your device, the earlier version, it

was circular, wasn't it?
A. The -- yes.
Q. And the subsequent mitral versions of your device, they're also circular, right?
A. They are.
Q. The CardiAQ device is circular, but the Neovasc Tiara device, to your knowledge, is D-shaped, correct?
A. The atrial portion is D-shaped.
Q. The atrial portion of the Neovasc device is D-shaped, correct?
A. Yes.
Q. Now, the idea of opposing anchors designed to capture tissue, that was used in your early thinking for your aortic designs, correct?
A. That is correct.
Q. That was an idea that you carried forward from your aortic work to your mitral work, correct?
A. That's correct.
Q. Now, your device, the CardiAQ device, it has a number of equidistant anchors on both the top atrial side and the bottom ventricular side, correct?
A. Yes.
Q. Having equidistance anchors on both sides, the atrial side on the top and ventricular side on the bottom, that's also something that carried forward from your early thinking on an

aortic design, correct?
A. Yes.
Q. Your valve, your design has 12 identical anchors on the top and 12 identical anchors on the bottom, correct?
A. They're not identical anchors.
Q. Well, the shape and size of the 12 ventricular anchors on the circle, each of those is shaped and sized identically, correct?
A. They're not identical. There are shapes and sizes. They
12:57 have different shapes and different sizes.
Q. Well, in Rev. C through Rev. E, do you remember those revisions?
A. Yes.
Q. The different revisions there for those designs, those anchors were equally spaced between them, correct?
A. Those anchors were.
Q. And they had equal lengths, correct?
A. Which anchors are we talking about, the atrial or ventricular?
12:57 Q. Ventricular.
A. Yes.
Q. Now, the Tiara device, it's got three anchors on the bottom, ventricular side, correct?
A. Yes. You're calling them anchors. That's good. They're tabs, as described by -- anchoring tabs, by your patent.

Q. Either way, either way. Tabs, anchors, there's three of them, right?
A. Yes.
Q. To your knowledge, their diameters, their exact sizing at an engineering machine level, they're not the same for your device, are they?
A. No.
Q. Your device doesn't have radio-opaque markers, does it?
A. The whole device is radio-opaque.
12:58 Q. You don't have radio-opaque markers, correct?
A. Not specifically designated.
Q. Thank you. Your device doesn't rely on what's called radial force, sometimes called friction, correct?
A. It exerts radial force, but it would be wrong to understand that radial force is a fixation force.
Q. In other words, there's no friction fit that you intend to hold the device in place, correct?
A. Friction and radial force is not intended to maintain the device in mitral position.
12:59 Q. That's something that you've been advertising since 2009, that you think using radial force is something that you want to avoid in your device, correct?
A. It's unavoidable, but it is not forced to rely upon fixation. I have always said that, that you can't do it with radial force alone.

Q. That's something that you've been publicly advertising about your device since at least the middle of 2009, correct?
A. I've spoken about it.
Q. Publicly, correct?
A. Yes.
Q. Now, although some features carry forward from your original aortic design work to your mitral designs, the CardiAQ device that you have today, what you called Generation 2 this morning, that's not the same version that your company showed
01:00 Neovasc back in 2009 or 2010, correct?
A. Generation 2 has the same elements, but it's shaped differently.
Q. It's got some differences, doesn't it, sir?
A. Dimensional.
Q. More than just dimensional, correct?
A. Not -- it has the atrial anchors. It has the ventricular anchors. It's just not cylindrical-shaped. It's basically covered with cloth. But the basic elements of the two, the concepts are the same.
01:00 Q. All right. Let's go through this in more detail then. The device that you first implanted in a human being, Revision J in 2012, Revision J wasn't shown to Neovasc, correct?
A. Yes, that is correct.
Q. And by the way, the person who actually does that human implantation, that's an interventional cardiologist, correct?

A. In this case, it's interventional cardiologist.
Q. Revision J had some design changes compared to the versions that were shown to Neovasc previously, correct?
A. There were changes made to it, yes.
Q. As one example, after your first human implantation in 2012, you changed the design by covering the metallic portion of those anchors with some fabric, correct?
A. In Gen. 1 and Gen. 2, yes.
Q. During that implantation in 2012, all of the metal tips on
01:01 those ventricular anchors were uncovered, correct?
A. Yes.
Q. And after that implantation, you studied the tissue, and the tissue showed that some blood had formed in channels of blood vessels in the tissue that you looked at, correct?
A. I'm not quite understanding your question. Please repeat it.
Q. After that first implantation, the study of the tissue showed that blood in channels of blood vessels had formed stripes, correct?
01:02 A. The stripes were not formed in channels of blood vessels.
MR. GRAVES: Your Honor, I'd like to play Volume 3 of Dr. Quadri's deposition, pages 627, 21 to 628, 16.
THE COURT: Give me those again.
MR. GRAVES: Volume 3, page 627, line 21, and page 628, line 16.

THE COURT: 627, line 23 or 27?
MR. GRAVES: Sorry. Line 21 to 628, 16.
THE COURT: I thought you said 27. It only goes up to 25. Any objection?
MS. LEA: Your Honor, I don't believe it's --
THE COURT: So I think the issue is the terminology used in line -- can I see you quickly at sidebar for a second.
SIDEBAR:
THE COURT: Tell me what the problem is, using the stripes? Is that the gist of the --
01:04
MS. LEA: I think so. I'm not sure --
THE COURT: He's talking about stripes now.
MR. GRAVES: This is really the question. "Have you participated -- channels that had been disrupted during the procedure? What do you mean by channels? Channels of blood vessels, veins." So I kind of combined the question.
THE COURT: Just to clarify what he's talking about, he's talking about stripes. I think you can have it. He was just talking about stripes, right, the way he answered it?
01:05
MR. GRAVES: He did, I think so.
THE COURT: I think that's the issue. I'm not sure stripes correlate to anything he's talking about there.
MR. GRAVES: All right.
(End sidebar.)
BY MR. GRAVES:

Q. Dr. Quadri, when I asked you that question a moment ago -- I'm going to rephrase it. After this implantation, when you studied the tissue, you found that blood had gathered in channels, correct?
A. From what I remember from the testimony, I said blood has gathered in tissue due to disruption of channels.
Q. And you've referred to the channels, that blood there, as tiger stripes or zebra stripes, correct?
A. That's descriptive.
01:06 Q. If you can look at 5004 in your binder.
MR. GRAVES: Bill, let's hold that for a moment.
Q. Dr. Quadri, is that a true and correct copy of a photograph from the study of the tissue showing your device surrounded by tissue with the blood stripes that you've just described?
MS. LEA: Your Honor, I'd like to object to this exhibit based on the MIL.
MR. GRAVES: Your Honor, I've done everything as strictly as we've discussed.
01:07 THE COURT: I'm not sure I understand the basis for the objection. I mean, do you want to talk about it at sidebar quickly?
MS. LEA: I think so.
SIDEBAR:
MS. LEA: It was established during examination that

the staining had nothing to do with the device or the heart, and now we're going to look at the heart and start talking about the bruising and staining or the channels in the heart for no purpose. I didn't show any pictures of the heart from this patient.

THE COURT: So I didn't realize it was the same patient.

MR. GRAVES: A couple of background pointers. I haven't even mentioned this is a human or that the person died. I've referred to it as a study of tissue, to be very sensitive here. The anchors here, you can see the type of structure here, I'm going to use that to establish why the changes were made. I'm not going to say it was a human. I'm not going to say the patient died.

THE COURT: I think that's all right.

(End sidebar.)

Q. All right. Dr. Quadri, that is a true and correct copy of a photograph from the implantation study that we've been discussing; is that correct?

A. That is correct.

Q. And that's a photograph that you're personally familiar with, correct?

A. I've seen this, yes.

Q. And if we look at that photograph, and we'll put it up in a moment, but I want to confirm first, that's your device and

some tissue. And the photograph shows the anchors of your device in the tissue that you studied, correct?
A. Yes. I would like to comment on that.
Q. Let's put this tissue up on the screen, sir. Now, if we look at this photograph, sir, this is your device in the middle; is that correct?
A. That is correct.
Q. These are your anchors on the bottom of your device here, correct?
01:10 A. That is correct.
Q. And in the tissue we see the striping here that you've referred to as tiger stripes or zebra stripes, correct?
A. Correct.
Q. Now, you personally yourself didn't believe that the bruising, the tiger stripes was caused by the metallic tips of the anchors, correct?
A. Yes.
Q. You believe that it was caused by staining through the gravitation of blood, correct?
01:10 A. Correct.
Q. And just last Wednesday, one week ago, you testified that you had not heard anyone express a contrary view, correct?
A. I qualified that answer.
Q. You testified that so far as you knew, nobody directly or indirectly had expressed any doubt about your conclusion,

correct?
A. That is correct.
Q. And you gave that testimony under oath, didn't you, sir?
A. Yes.
Q. That testimony was false, wasn't it, sir?
A. It's -- I said nobody agreed or disagreed. There was discussion about it. I mean, you can have an opinion and other people can disagree with what you're saying.
Q. So the testimony you gave under oath that you had never heard anyone express a contrary view just one week ago, that testimony wasn't correct, was it?
A. Actually, for that particular part of staining, the explanation was accepted.
Q. Sir, respectfully, my client has the same right as yours to get clear answers to clear questions in this courthouse.
When you testified just one week ago that no one had expressed a contrary view, that testimony wasn't correct, was it?
A. In my opinion, it was correct.
Q. Well, in fact, your investors hired a renowned pathologist to look at what caused that zebra striping, correct?
A. They were doing due diligence.
Q. They did that, didn't they?
A. They hired -- yes, they did.
Q. And it turns out that that pathologist, Dr. Renu Virmani,

she felt, among other things, that there might be too much exposed metal and too many anchors, correct?
A. She did comment on that.
Q. She suggested the possibility that exposed anchors or metal might have caused that tiger striping we just saw in the photograph, correct?
A. That is -- that is a deduction.
Q. You disagreed with her, didn't you?
A. She didn't say that.
01:12 Q. You disagreed with her, didn't you?
A. She didn't say that.
Q. I'm going to ask you one more time. You disagreed with her, didn't you?
A. I disagreed with her on other issues, but this was not an issue of disagreement.
Q. Your investors, Oribmed and Dr. Virmani, both disagreed with you on this issue, correct?
MS. LEA: Objection, Your Honor. Hearsay.
A. That is not on record.
01:13 Q. I'm sorry?
A. That is not correct.
Q. Okay. Let's play Quadri Volume 3.
MS. LEA: Objection.
THE COURT: I'll sustain it on asked and answered.
MR. GRAVES: The question was about the investors

Orbimed and Dr. Virmani both disagreeing with him. That was the first time I asked it, Your Honor, respectfully.

THE COURT: I'm sorry. I didn't realize you added in the second doctor. I'm going to overrule it on hearsay. Go ahead.

Q. Your investors, Orbimed and Dr. Virmani, both disagreed with you on this issue, correct?

A. They disagreed -- they wanted to do due diligence because they wanted to -- Orbimed was investing in our company. They wanted an opinion of an outside pathologist. The discussion was held, and it was -- she pointed out some improvement or some concerns that she had, but she did not outright disagree with me that these stripes, what we're calling zebra stripes, were staining and lividity. That is the best of my recollection.

MR. GRAVES: Let's play Dr. Quadri's deposition -- or may I play, Your Honor, Volume 3, page 663, lines 9 through 18.

THE COURT: If you look at page 663, line 19, that's unresolved, I take it?

MS. LEA: That's right, Your Honor.

MR. GRAVES: Hold on one moment. That's correct, Your Honor.

THE COURT: I'm sorry. I need to see you at sidebar about this one.

SIDEBAR:

THE COURT: She starts objecting in the record pages before. So I can't quickly make a ruling on this without figuring out what she's already objecting to three pages back. So this is why I tell you to sort it out before this, right?

MR GRAVES: Well, the question here seems pretty easily framed. "We have two categories of people who disagreed with your opinion, Orbimed, who you indicated were not a medical professional" --

THE COURT: He says, "Uh-Huh."

01:17 MR. GRAVES: "And Dr. Virmani."

THE COURT: She has an objection. I can't figure out --

MS. LEA: There are a lot of opinions, Your Honor, and there were some that were disagreed with and some that weren't. That was the whole problem with this line of testimony.

MR. GRAVES: The original question, this is all credibility, I said, "You testified that no one disagreed with you," and he admitted that he did --

MS. LEA: About the channels.

01:17 THE COURT: Right.

MR. GRAVES: Later on he admitted there was --

MR. FLYNN: If I may, that objection was misstated. That objection was made repeatedly throughout the day. If you study the transcript, you will find it's unfounded --

THE COURT: I understand that, but I'm trying to

follow it back to make a ruling on this.

MR. GRAVES: It seems there's not a record or mistake in two people --

THE COURT: You have in this question -- she's indicated he or she is a well qualified, respected medical professional --

MR. GRAVES: I don't think Ms. Lea objected to that.

MS. LEA: First of all, here's the objection, Your Honor, the doctor --

01:18 THE COURT: Whether I agree to them or disagree is not hearsay.

MR. GRAVES: I'm not offering it for the truth.

THE COURT: He's also not asking what they said.

MS. LEA: If you go back, you can see where they talked about it. And other issues besides the channels -- that was the problem with this, trying to get this little sound bite here at the end to make it look like there's a disagreement about the metal in the channels.

THE COURT: I just can't resolve this standing here

01:19 without taking the time to go back and read however many pages there are. If you want to try and elicit this part again, I'll let you have it --

MR. GRAVES: Okay.

THE COURT: -- if you want to make the record on that.

MR. GRAVES: I don't think the dispute was about the

doctor's qualifications. I don't think that point was disputed.

THE COURT: The point you're disputing is whether or not she disagreed with him.

MR. GRAVES: Correct. When he first said he hadn't heard anybody express disagreement.

THE COURT: (Reading.)

MS. LEA: He's taking one opinion out of many and trying to make it a disagreement about that one opinion. There are a lot of opinions made.

01:19

THE COURT: That you can deal with on redirect, but if you guys have this situation where there's an objection that you want to play something, you have to give it to me. This one is particularly difficult when she starts making arguments about the record --

MS. LEA: We're still going into the safety line, Your Honor. It's all about the safety.

THE COURT: He needs to stick to the impact on it making change. Now, he's entitled to impeach, and he's going

01:20

to be asking and answering the same questions differently. That's not a motion in limine. That's just a fact of trial.

MR. GRAVES: Correct. This is purely impeachment. The guy said something under oath that wasn't true.

MS. LEA: It was not impeachment, Your Honor. I was at this deposition. It was objected to by the attorney, and it

was one of the longest depositions I ever sat through.

THE COURT: That doesn't have anything to do with here today --

MR. FLYNN: I don't want to bicker at sidebar. That's not true.

THE COURT: Right now he's just trying to impeach on inconsistent statement, and the way this record is in front of me, it's very hard for me to tell.

MS. LEA: There's a reason why they tried to get that
01:21 sound bite going through different opinions --

MR. FLYNN: There's going to be a document where the admission is made clearly by Mr. Ratz in black and white. There's a notion there's different opinions, and if there's any merits to that objection --

THE COURT: I take it the idea that it's a new device, you have a lot of people looking at it and saying that something is brilliant and something is crazy and you have all sorts of opinions all over the map about it. You can redirect on that. If he wants to pick out one opinion and you want to
01:21 slam it back that there were 50 people and only three disagree, that's fine. I don't want you to be rude to the witness either. Impeaching is fine. He's trying to answer your questions, I think.

MR. GRAVES: Okay.

THE COURT: So you can play this, but then I want you

to give him the opportunity to explain.
(End sidebar.)
MR. GRAVES: All right. So we are going to play 663, 9 to 18, please, Bill.
(Video played.)
THE COURT: Now, I'm going to note that the next line of this is Ms. Lea objecting at the deposition, and for the time being, I am overruling her deposition objection.
Q. Dr. Quadri, you indicated that you wanted to say more about the viewpoints of yourself and Dr. Virmani. What specifically did you want to say, sir?
A. The discussion with Dr. Virmani was that the explanation for the staining was -- she agreed with the explanation for the staining on the heart, more described as zebra. She raised -- and so that we agreed upon. And she raised issues about the exposed metal on the frame, and she also raised issues about, you know, any bleeding or tamponade that could occur. So that was a discussion.
There was no hardline disagreement between her and me or my company for that matter. And that was my take-home message, that I need to work with the device, and we were concerned about the metallic exposure as well. So that's what -- and the concerns that she had raised, we had raised about the staining that that was further, you know, studied by us to have more proof of that. So it was a discussion. There was no "I agree

with you," or "I don't agree you." That's what I remember from that conference.
Q. And regardless, we started all of this by discussing the way that your devices have changed over time when compared with the devices shown to Neovasc. And what happened here after this back and forth with you and Dr. Virmani and the others was that you went and conducted more animal studies, correct?
A. I did go back into animals.
Q. And in the end, your company changed the anchors to cover
01:25 up those metallic tips after the episode with the tiger stripes, correct?
A. That is correct.
Q. In addition, when we again compare your more current devices to the Revisions C through E that Neovasc saw back in 2009 and 2010, your current devices also have changes to the length of the anchors, correct?
A. We have studied the length of the anchors and adjusted accordingly.
Q. And you have changes to the width of the anchors as well,
01:25 correct?
A. We have done that.
Q. You also have changes to the place where the anchors are originating in the device, correct?
A. Yes. I have to look at a device to be positive on that.
Q. Well, you've testified to that before previously, haven't

you?
A. That is correct.
Q. And in your Gen. 2 device today, it no longer has anchors that are intended to anchor on the mitral annulus, correct?
A. They're not intended to anchor on the mitral annulus.
Q. So the clamping of tissue with the two rings of anchors that Mr. Ratz and others spoke about back in 2009 as an important aspect of those devices, that's no longer something you do, correct?
01:26 A. Well, that concept we got away from when we started. And the whole anchoring mechanism changed. But we went -- we started with clamping, and there's always foreshortening in stents, and we have exaggerated that. But it wasn't the pinching that we were talking about. So yes, we have changed.
And the other aspect of those anchors being raised to the atrium had sound medical reasons. And so that's what you do. You make a device better. You want to improve in your next generation. You want to make it friendlier to human body. So that's what we were doing.
01:27 Q. There were sound medical reasons to prefer your current devices over the original versions that Neovasc saw back in 2009 and 2010; is that fair?
A. Yes. If I can explain those medical reasons.
Q. Well, just to go through these changes so we've got the catalog, sir, your Generation 2 device also made a change by

putting a sealing skirt around the annular middle portion of the device to better protect against leakage, correct?
A. Yes.
Q. That was to prevent a problem known as backwards flow; is that right?
A. That is to prevent mitral regurgitation.
Q. By the way, your first in-human implantation that you've described in 2012, that was actually long after your relationship with Neovasc ended, correct?
01:28 A. Yes, that would be correct.
Q. And what all of this means is that Revisions C through E that Neovasc saw, those are not your current designs anymore, correct?
A. They're based on the same principles, but the design is improved and much kinder to the human body.
Q. And you're not yourself planning to implant Revisions C, D or E into an animal or a human, are you?
A. I don't see the need to.
Q. I think you even said yesterday that you're still working
01:28 on your device even today, correct?
A. Yes.
Q. And just to be clear, no regulatory body has approved your device for sale, correct?
A. No, nobody else's either.
Q. So there haven't been any sales; is that right?

A. No.
Q. You haven't made any sales of your product, and nobody has signed a contract telling you they will buy anything from you, correct?
A. No.
Q. So let's talk about the public domain. You mentioned a conference called TCT. That's a very important conference in the heart valve industry, correct?
A. That's one of them, yes, that is true.
01:29 Q. Some of the others are TVT, Euro PCR, and there's others, correct?
A. Yes.
Q. You yourself, you've attend the TCT conference more than once, correct?
A. I have.
Q. It's open to the public, correct?
A. It's open to the public.
Q. You're aware in your own personal experience that lots of people in the heart valve industry, surgeons and also people
01:29 who designed devices go to these conferences, correct?
A. Yes.
Q. It's common knowledge that this TCT conference is well known in the industry, and it's actually a premier conference in the industry, correct?
A. That is correct.

Q. And in your experience at TCT, companies will be in an auditorium or a lecture hall and they'll present information about their medical devices, correct?
A. Well, it is correct, but I'll have to point out that it's not the company presenting.
Q. Okay. Sometimes a surgeon or a physician will do the presentation; is that fair?
A. All the time. This meeting is not a trade show. It's a scientific meeting. So cardiologists, surgeons, physicians
01:30 present to peers. Industry is there. Industry has a certain number of presentations designated to them in the developmental slot. But the industry is not the presenter in this meeting.
Q. Fair enough. Nobody needs to sign a non-disclosure agreement to go to TCT, correct?
A. No.
Q. CardiAQ gave presentations at the TCT conference because it was a good way for you to get the attention of the industry for your device, fair?
A. It was more for getting attention of my colleagues that I
01:31 have a solution here. "Hey, guys. You can treat this, and I have a solution." That was my intention.
Q. You yourself have actually been a presenter --
A. Yes.
Q. -- at TCT involving your own device, correct?
A. I have presented at TCT.

Q. In fact, in September of 2009, you helped to give a presentation of information about your device to a number of people in a room at the TCT conference, correct?
A. I did not present in September of 2009.
Q. That was one of your surgeons, Dr. Bavaria?
A. Yes.
Q. You did help him put together the materials and considered the materials that would be put into those slides, correct?
A. Yes.
01:31 Q. And so you looked at those slides, correct?
A. I didn't look at the slides. I was a practicing heart surgeon, so I didn't have the time. My colleague, Mr. Ratz, he basically was very good at putting together information. He had that -- there was a funnel of information going out, and we always had an understanding that he would look at them.
Q. You've since looked at those slides, haven't you?
A. I have looked at the slides.
Q. You've given testimony about them, correct?
A. Yes.
01:32 Q. All right. Let's pull out Exhibit 261 in your binder.
MS. LEA: Objection, Your Honor. He just testified that he did not see the presentation, did not give the presentation and was not involved in making the presentation.
MR. GRAVES: He doesn't need to be if he's a company officer and he's read the presentation.

THE COURT: I think that's correct. Overruled.
Q. Doctor, if you'll turn to 261, is this, sir, the document that Dr. Joseph Bavaria gave for TCT and that you subsequently looked at later and gave testimony about?
A. That is correct.
Q. Now, it says on the front, "TCT Company Overview." Just to be clear, that is the conference that we've been discussing, correct?
A. Yes.
01:33 Q. And as you just described, a surgeon, a doctor came and gave information to other people in the industry about your device, correct?
A. Yes.
MR. GRAVES: Let's turn, Bill, to slide 6 of this slide presentation.
Q. If we look at the wording here, there's three bullet points. Do you see that, Dr. Quadri?
A. Yes.
Q. And you say here in the second bullet point, "Preservation
01:33 of the Subvalvular Apparatus."
A. Yes.
Q. Those words do appear in this presentation, correct?
A. Yes.
Q. Your device preserves the leaflets and the chordae, correct?

A. Preserves the subvalvular apparatus. More appropriate to say it's chordal-sparing.
Q. Fair enough. Either way, you preserve those natural structures, and that's something that you weren't shy about disclosing at TCT, correct?
A. No. But to qualify my answer, this subvalvular apparatus preservation is a part of mitral valve replacement that we practice in cardiac surgery. It's not a new concept.
Q. I'm sure it is. Thank you.
01:34 The third bullet point says "Annular Anchoring Without Relying on Radial Force."
A. Right.
Q. Now, radial force we talked about a bit earlier, Dr. Quadri. This is what you and Mr. Ratz -- what you strove to do in 2009 was not to rely on radial force in anchoring your device in the mitral annulus, fair?
A. That's fair.
Q. That was your goal?
A. We did not want to rely on radial force, that is correct.
01:34 Q. Fair enough. You also say here, "Annular anchoring," on these CardiAQ presentation slides, correct?
A. Correct.
Q. And annular anchoring, that means you're literally anchoring on the mitral annulus, correct?
A. That is true.

Q. And you do that by anchoring above and below that structure in the middle that you described called the annulus, correct?
A. Yes.
Q. Annular anchoring, as of September 2009 at least, that's just not secret, is it?
A. No. Annular anchoring is never secret. The question is how do you do it. That's the secret.
Q. And anybody can try to do it in any different way because
01:35 the basic concept was known and wasn't new, correct?
A. I want to agree with you, but the problem is it cannot be -- annular anchoring can be done in several ways. CardiAQ's way was a unique way, and we described that. So some other company can, and Edwards Lifesciences were doing some annular anchoring as well, but they had a different method of doing it.
Q. In fact, there were a lot of different methods that you were personally aware of of annular anchoring out there in the heart valve industry as of 2009, correct?
A. There weren't many.
01:36 Q. There were some that you knew of, correct?
A. They were trying, without success.
Q. Fair enough. But the concept was out there, right?
A. Yeah, so that's basically where you anchor a valve, into the annulus.
Q. I just want to be clear, regardless how you do it, no one

is going to be able to come in and say anchoring on both sides of the annulus is some big secret, correct?
A. No, that's not a secret.
MR. GRAVES: All right. Let's turn to page 7 of this slide. I'm sorry. Let's stay on this page. I apologize, Bill.
Q. The photo here is not very good, Dr. Quadri, but if I understand correctly, this is an earlier version of one of your frames, correct?
01:36 A. Yes. That's the aortic version.
Q. Right, the aortic version that you started with. And even in that version, as we discussed earlier, we can see that there are anchors around the bottom that are evenly spaced, correct?
A. Yes.
Q. We've got one there, you got one there, one there. Not a very clear photo, but we can see that there are equally based anchors, correct?
A. Yes, that is correct.
Q. And the original presentation slides were color, correct?
01:37 A. Yes.
Q. Do you mind if I show a color version of this?
A. No. Please go ahead.
MR. GRAVES: Thank you, Bill. Let's put it up.
Q. So we have a little bit of better visibility here. Now, we can see that there's anchors equally spaced on the bottom

side, correct?
A. Right.
Q. And we can see that there are anchors evenly spaced on the top side, correct?
A. That's correct.
Q. And this was the clamping that started in the aortic design and carried forward to the mitral design; is that fair?
A. That is fair.
Q. And more or less, the shape of these anchors is the same, correct?
A. Yes. Like them to be the -- they're not the same because you don't see the whole anchor. These anchors were cut out from inside the stent and kind of turned that way. So there is bends in this anchor that is not visible on this. So if you think it's taking out a prong like this, becomes an anchor. But we changed this whole geometry, so it's not the same. For the mitral device, we did not have an anchor of that configuration.
Q. As of September 2009 at least, there was no secret in placing equally spaced anchors on both sides of an annulus to clamp, correct?
A. That is correct.
MR. GRAVES: Let's turn over, Bill, to the next slide, slide 7.
Q. If I understand correctly, sir, this picture here shows

one of the versions that you described this morning of your device actually seen at the mitral annulus, correct?
A. At the annulus, yes.
Q. And that middle portion of the device that's aligned with the annulus, that's the annular portion, correct?
A. Yes. So the circle is showing the annulus, the white circle on the side.
Q. And you've got an annular portion on the device, correct?
A. This one here. That's about it.
01:39 Q. And the top part up here, just to help everybody with the anatomy, that's the atrial portion, correct?
A. Yes.
Q. And this -- we keep saying "bottom" and "ventricular." That's the ventricular portion down here, right?
A. Right.
Q. So regardless what version of your device this is, at least as of September 2009, an annular portion, an atrial portion and a ventricular portion on both sides of the mitral annulus, that's not secret either, is it?
01:39 A. No. We show it here.
Q. Now, September 2009, that's still when you and Mr. Ratz were in the midst of your work with Neovasc, correct?
A. We were.
Q. Now, you also had a website for your company, CardiAQ, that was up and running at least by January 2010, correct?

A. Correct.
Q. And you've seen and given testimony about pages from that website from January 2010, correct?
A. Yes.
Q. Let's look at Exhibit 263 in your binder, please.
Dr. Quadri, if you look at 263, is that a true and correct copy of a page from your website that was visible in January of 2010?
A. Yes.
01:40 Q. And we actually see here the same picture that we just saw a minute ago; is that right?
A. Yes.
Q. If you'll turn in your binder, please, to Exhibit 265. This is also a true and correct copy of a technology profile document that was available on your website by January of 2010, correct?
A. Yes.
Q. And if we look toward the bottom of this page, we see the same picture with some text here. And it says, quote,
01:41 "Anchoring. With the valve in position, the sheath is retracted fully. Foreshortening of the frame creates a clamping action that anchors the valve above and below the annulus." Correct?
A. That is correct.
Q. At least as of January 2010, that was up on your website

for anyone to look at, correct?
A. Yes.
Q. January 2010 was still during the time period when you and Mr. Ratz were working with Neovasc; is that correct?
A. That is correct.
Q. Now, you described this morning that in the time of your career you've been involved in a number of patent applications; is that right?
A. I have.
01:41 Q. Some of them have been on behalf of CardiAQ, correct?
A. That is true.
Q. And you filed a patent application in the fall of 2010 that was published around April 1 of 2010, correct?
A. Published -- it takes about 18 months from a provisional.
Q. Let's take a look at 260 in your binder, and we can check the date.
A. 266?
Q. 260. I'm sorry. Exhibit 260 is a true and correct copy of one of your patent applications; is that correct?
01:42 A. That is correct.
Q. And if we see on the top right hand, it says "Pub. Date, April 1, 2010." That's the publication date, correct?
A. Yes, yes.
Q. So that was published on April 1 of 2010; is that right?
A. This was published, yes.

Q. And you know in your own personal experience that if a patent application is published, someone could type in your name at the U.S. Patent Office website, and they'd be able to pull this up; is that correct?
A. Yes.
Q. Now, you actually filed this patent application several months before April 1, 2010, correct?
A. Yes.
Q. And you understood at the time you filed it that it would be eventually made available to the world on the Internet, correct?
A. Yes.
Q. And so you decided several months before April 1, 2010, that every word in this patent application would eventually be made public for the world to see, correct?
A. That is correct.
Q. Okay. And just to set our dates again, sir, April 1, 2010, that's toward the tail end of your relationship with Neovasc, correct?
A. That is correct.
Q. Let's look at figure 12 of this document. This is a drawing of Rev. C of your device, correct?
A. Yes.
Q. That's a yes?
A. Yes.

Q. This shows the frame of a stent for percutaneous mitral valve insertion, correct?
A. That is correct.
Q. And if I look down at the bottom, I see these little tabs here, those are mushroom-shaped tabs, aren't they?
A. Yes. The bottom ones, these.
Q. Yes. Thank you. And those mushroom-shaped tabs, they lock into the delivery device that's necessary to deliver this frame into the human heart, correct?
01:44 A. That is correct.
Q. They kind of snap in like a button; is that fair?
A. Not quite.
Q. They snap in and hold it in place; fair enough?
A. Yes.
Q. All right. Now, we can see in this drawing both foreshortening and non-foreshortening sections, correct?
A. Right.
Q. We can see atrial and ventricular anchors, correct?
A. Yes.
01:44 MR. GRAVES: Why don't we turn over to figure 11, Bill, the previous figure.
Q. This is another drawing in the same patent application, correct?
A. Yes.
Q. And we see here the two rows of anchors again, don't we?

A. Yes.
Q. We see here anchors formed by V-shaped support struts, correct?
A. Yes.
Q. That's like a little bit of a letter V there in the anchors at the end; is that right?
A. Yes. The little projections, these are the atrial anchors.
Q. Right there?
01:45 A. Yeah.
Q. And these are anchors that were intended to atraumatically engage the atrial side of the mitral annulus, correct?
A. Yes.
Q. Now, if we look at figure 14 in this same document, this picture shows a version of your device in a drawing or a cartoon of the mitral annulus, correct?
A. Yes.
Q. And it shows foreshortening sections or a foreshortening section with kind of diamond-shaped cells, correct?
01:46 A. Yes.
Q. Now, this patent application from April 1, 2010, it also discloses atrial anchors in the first bend that curves the anchors radially outward and a second bend that curves the anchors in a second direction, correct?
A. Yes.

MR. GRAVES: Now I want to look at figures 20 and 21, Bill, if we can, please.

Q. Sir, these are also drawings that appeared in the same April 1, 2010 patent application, correct?

A. Yes.

Q. Will you please hold up the mandrel that you showed the jury this morning, please?

MR. GRAVES: Your Honor, may I approach to get it?

THE COURT: Yes.

01:46 Q. I believe, Dr. Quadri, you've testified this morning that this was a mandrel that you took to Neovasc when you went and met them in Vancouver in about June of 2009; is that right?

A. Yes.

Q. Now, this is a mandrel along the lines of the one that you took with you to visit Neovasc in June 2009 shown here in figures 20 and 21, correct?

A. Yes.

Q. So as of April 20 -- sorry, April 1, 2010, the mandrel was public, correct?

01:47 A. Yes.

Q. And so, Dr. Quadri, even though CardiAQ today claims the mandrel as trade secret claim number 5 in this lawsuit in May of 2016, we see it here published on April 1, 2010; is that correct?

A. Yes.

Q. All right. This morning, you looked at Exhibit 615. I have that also marked as Exhibit 2123, but I think we can look at 615 in your binder from this morning, sir.

Now, this is the presentation that you personally gave at the TCT conference that we discussed in September of 2010, correct?

A. Yes.

Q. I think you mentioned you got up in a room and you talked for about ten minutes; is that right?

01:48 A. Yeah.

Q. There was a room of people kind of in a lecture hall?

A. Yes.

Q. But you didn't require that those people sign non-disclosure agreements to come into the room and hear the presentation, correct?

A. That is correct.

Q. In your personal experience, oftentimes slides from the TCT conference become available on the Internet, correct?

A. Yes.

01:48 Q. Your company has not been involved in sending take-down notices to anybody who has put up those slides on the Internet afterwards, correct?

A. I am unaware of that, and this was not my tradition in my company. We were certainly sensitive to that, and we instructed the conferences to not do so.

Q. Nonetheless, your company to your knowledge has not gone around sending take-down notices to websites that have posted these slides, correct?
A. To my knowledge, no.
Q. All right. If we look at slide 9 of this presentation, sir, this is one of the versions of Rev. E that we looked at earlier today, correct?
A. Yes.
Q. And this is an engineering drawing also of that same device, correct?
A. Right.
Q. We see here the wider portion on the ventricular side compared to the narrower portion on the atrial side, correct?
A. That is correct.
Q. And we can see again these V-shaped anchors; is that correct?
A. Yes.
Q. If I look closely, I can see the mushroom-shaped locking tabs on this device as well, correct?
A. Where do you see them?
Q. It looks like I've got them right there.
A. Yes.
MR. GRAVES: Okay. Thank you, Bill.
Q. If we look at slide 6 of this presentation slide that you gave, here is another one that mentions chordal-sparing.

A. Yes.
Q. And again, you do everything you can not to damage the chordae when you implant your device, correct?
A. Yes.
Q. You personally believe there's good medical reasons not to damage the chordae, and that's why you try to avoid it?
A. We try to preserve them, yes, most of them.
Q. And you try to preserve them because at least in your view there's good medical reasons to preserve them and not tear them
01:50 and damage them, correct?
A. Yes. But there is mitral valve replacement where we do sever them, all of them.
Q. There are some types of devices in the world where you cut the stuff out surgically, but in your device, you've always made it your goal to preserve and not damage those tissue structures called chordae?
A. If I can just say that a little differently, in my device we want to preserve as many chordae as possible.
Q. Thank you. Now, on slide 7, the next page, again, here we
01:51 see some phrasing we saw before, "Preserve the MV Apparatus." That's a fancy way of saying let's be careful and not damage all that tissue, the leaflets and the chordae; fair enough?
A. Yes.
Q. Now, you've also seen a presentation that Dr. Bavaria gave on behalf of CardiAQ at a presentation in Dallas, Texas in

October of 2010 even though you weren't there yourself, correct?
A. I do not remember seeing that presentation.
Q. Do you remember giving testimony and reviewing and speaking about a document that Dr. Bavaria presented in October of 2010?
A. I don't have a recollection of that. If I could see the presentation, I could tell.
MR. GRAVES: Why don't we take a look at tab 266.
01:52 Don't put it up yet, Bill.
Q. Let's just take a look. Can you look at tab 266 in the binder that I gave you.
A. Yes.
Q. Does that refresh your recollection that you've given testimony and seen before a presentation that Dr. Joseph Bavaria gave in October 2010 in Dallas --
A. Yes.
Q. -- about CardiAQ's device?
A. Yes.
01:52 Q. Let's put up the front page of Exhibit 266. Is this a true and correct copy of that presentation, sir?
A. Yes.
Q. Right here on the front we've got a drawing of one of your versions of your device, kind of like the other ones we looked at inside the mitral valve in a cartoon, correct?

A. Yes. It's -- closest that's come to it is Revision B.
Q. Sure. That's like an older version, just kind of a cartoon; fair enough?
A. Yes.
Q. On the other hand, if we turn to slide 20 --
MR. GRAVES: Let's do that, Bill.
Q. -- this one gives us more detail than that cartoon on the front page, correct?
A. About the fixation that we've seen before, yeah.
01:53 Q. In fact, that's that same photograph that we looked at, Exhibit 2634, that was a huge, huge thing?
A. Yeah.
Q. This is the one you testified shows going behind the leaflets and through the chordae?
A. That is true.
Q. As of October 2010, sir, the fixation of the CardiAQ device was not secret because CardiAQ had showed it to the world, correct?
A. I would have to disagree with you on that.
01:53 MR. GRAVES: Your Honor, I would like to play Volume 1 of Dr. Quadri's deposition transcript, page 261, lines 18 to 22.
THE COURT: Any objection?
MS. LEA: Yes, Your Honor. I objected at the time of the depo as well.

THE COURT: You object to what?

MS. LEA: I made the objection at the time of the deposition as well that the question was vague and ambiguous. He's asking a different question than what he's asking him now.

MR. GRAVES: If we look at line 13, page 261, lines 13 to --

THE COURT: I don't see an objection to what he asks in 18 and 20.

MS. LEA: It's the same question that he asked at 13, Your Honor. Then I objected and he repeated the question.

THE COURT: You objected to form.

MS. LEA: That's right.

THE COURT: And he rephrases the question.

MS. LEA: He did not rephrase the question, Your Honor. The objection stood. The witness answered quickly.

MR. GRAVES: There's nothing vague and ambiguous about the question. It's about as direct as it could be.

THE COURT: I don't see the objection in this testimony, but regardless, it's overruled.

01:55 Q. You testified that you showed it to the world, correct? That was your testimony?

A. Yes. But how I did it, I didn't show them. Yes, we showed the video.

Q. The photographs that we just looked at in this presentation, correct, Dr. Bavaria showed the world, correct?

A. That is correct.
Q. All right. Now, later on you had another patent application, and it was published around December of 2011; is that true?
A. I don't remember the patent.
Q. Take a look at tab 271 in your binder. Let me know if that refreshes your recollection.
A. Yes.
Q. All right. That's a patent application for your device
01:56 that was published on December 22, 2011, true?
A. Yes.
Q. This is a true and correct copy of that document, correct?
A. Right.
Q. All right. If we look at figures 1 and 2 in this application, these are Rev. E of your device, correct?
A. Yes.
Q. And as of December 2011, the Rev. E frame, at least through this application, was disclosed to the public through the patent application, correct?
01:57 A. Yes.
Q. Now, I'd like you to turn back to Exhibit 615, which we looked at a moment ago, and in particular at slide 9.
A. 615, yes.
Q. You testified that that also was Rev. E, correct?
A. Yes.

Q. And so you didn't just publish this in December of 2011. You published Rev. E in September 2010, correct?
A. Yes.
Q. Now, to be clear, with your December 2011 patent application, the Patent Office has never actually issued you a patent for that application, correct?
A. No.
Q. It's been rejected six times, correct?
A. I don't know the number.
01:58 Q. Is that a fair estimate?
A. Yes, if you say so.
Q. We also looked, sir, at a patent that was issued in the year 2014 when you gave testimony with your counsel this morning. Do you remember that?
A. Yes.
Q. That patent was about the delivery system for your device, correct? That's what was covered in the claims?
A. Yes.
Q. That wasn't a patent that was issued for the anchoring
01:58 system of your device, correct?
A. It was disclosed, but the claims were not anchoring. It was claimed later.
Q. In other words, there are words in a patent document that might be written there, but that doesn't mean that they're part of the claims on which the patent is issued; is that true?

A. Yes.
Q. That's a yes?
A. Yes.
Q. Okay. Now, you talked this morning a bit about your business relationship with Neovasc, and I wanted to talk again about that first contact with Neovasc that you mentioned. Take a look at Exhibit 552 in your binder, please. This is a true and correct copy of an e-mail that you received from Mr. Ratz on June 4, 2009; is that correct?
01:59 A. Yes.
MR. GRAVES: All right. Bill, we can put that up. Let's blow up that first part.
Q. It's true, sir, that Mr. Ratz wrote to you, "Forward: Neovasc surgical products," on June 4, 2009, correct?
A. Yes.
Q. And he said, "Found our issue for tissue supply and sewing. Just spoke with these guys. And they can do it all for us from tissue to cutting to assembly. They've been doing it for 20 years. These are the guys that Patrick Choy was
01:59 telling us about who are making the Sorin Mitroflow valves in British Columbia."
You did read those words when you got this e-mail, correct?
A. Yes.
Q. And you knew what the Sorin Mitroflow valve was?

A. Yes.
Q. You didn't know who at Neovasc had actually been working on it, did you?
A. I did not know the person, no.
Q. You mentioned this morning that you went to a meeting with Neovasc up in Vancouver in June of 2009.
A. I did.
Q. When you were there, you learned that they had another -- or they had a stent product of their own, a metal stent
02:00 product, a medical device that was called Reducer, correct?
A. Yes.
Q. And at that time you didn't ask Neovasc if they had any other products of their own that they were working on in addition to the Reducer, correct?
A. I did not -- I don't remember asking that question.
Q. All right. You described yesterday and this morning, sir, some of your background, your many years in working as a surgeon. I believe you told us that covering a portion of a prosthetic valve with tissue, that's something that you knew
02:00 about for a long time before you met Neovasc, correct?
A. Covering the portion of the valve?
Q. Covering a portion of a prosthetic valve, a replacement valve --
A. Yes.
Q. -- with tissue, that's something that had been out in the

industry to your knowledge for a long time, right?
A. Yes.
Q. And more generally, the concept or the idea, the desire to reduce or eliminate mitral regurgitation, that's also something that in your personal experience had been out there in the industry for a long time?
A. Yes.
Q. As you said yesterday, there are some things in the industry that are old standard techniques, correct?
02:01 A. Yes.
Q. Now, you didn't actually work with anybody at Neovasc while they were developing the Tiara device, correct?
A. That is correct, I did not.
Q. And you understand, because you've been involved in filing patent applications, that when you file a patent application to the U.S. Patent Office, the U.S. Patent Office is in charge of deciding what's an invention and what's not an invention, correct?
A. That is correct.
02:02 Q. And you understand that Neovasc was issued a patent by the U.S. Patent Office and it was an issued patent that you were giving testimony about earlier, correct?
A. That is correct.
Q. And you understand that that means that the United States Patent Office found that something in the claims of that patent

was inventive over old standard techniques, correct?
A. That's the basis of a patent issuance, but there are places where there's an overlap.
Q. Well, you understand that not everything that's written in a patent document is an invention, correct?
A. That is correct.
Q. In fact, a patent document, whether it's a patent application or an issued patent, it has a whole lot of words and mentions a lot of things that aren't inventive, correct?
02:03 A. Yes.
Q. In fact, if we look at the Neovasc patent that you had on the screen earlier with your own counsel, Exhibit 565.
MR. GRAVES: If we can look on page 46 of this document, Bill, please.
Q. There's something called the "Background of the Invention." Do you see that?
A. Yes.
Q. And you've seen that "Background of the Invention" in your own patent applications that you've worked on as well, correct?
02:03 A. Yes.
Q. And what's written in the background of the invention, you understand that that's not an invention, correct?
A. No. That is a description of the background.
Q. Sure enough. Let's go back to the first page, the very first page, the cover page of the patent. It has something

called "References Cited." Do you see that?
A. I do see that.
Q. If you look over on the second page of this document --
MR. GRAVES: Let's go to page 2, Bill.
Q. You see "References Cited" continuing, and there's a whole bunch of things listed here?
A. Right.
Q. And you've seen "References Cited" in your own patent applications that you've worked on, correct?
02:04 A. Yes.
Q. And you've heard that called "prior art"?
A. Right.
Q. People who submit patent applications will give the U.S. Patent Office documents and patent applications and slide presentations that other companies have done in the process of applying for a patent, correct?
A. That is correct.
Q. And if we look here, sir, at this document, we see your name in here, don't we?
02:04 A. Yes.
Q. We see your name several times, "Quadri, et al.," "Quadri," "Quadri, et al." That's you, correct?
A. Yes.
Q. Those are your patent applications, aren't they?
A. Yes.

Q. In fact, two of those are patent applications that we've just been talking about?
A. Yes.
Q. One of them disclosed Rev. C?
A. Right.
Q. One of them disclosed Rev. E?
A. Yes.
Q. And if we look over on the right side of the page, it says, "Other Publications." Do you see that?
02:05 A. Yes.
Q. There's one about CardiAQ. Do you see it up at the top?
A. Yes.
Q. There's another one, "June 2009, CardiAQ." Do you see that one?
A. Yes.
Q. There's another one -- where is it? "CardiAQ Technologies," looks like that's your website. Dr. Ruiz, he's the one who disclosed on your behalf at Euro PCR in May 2010, correct?
02:05 A. Correct.
Q. In other words, the references cited here that were sent to the Patent Office, that had a whole bunch of stuff about your device, correct?
A. Correct.
Q. Let's look at the claims in this patent toward the back of

the document. You've seen patent claims before in your own patent documents, haven't you?
A. I have.
Q. And you looked at these claims earlier today. Let's blow up claim 2 just by way of example. The method of claim 1 where at least a portion of the prosthetic valve is covered with tissue or a synthetic material, that's something that's been around for a long time, right?
A. Yes.
02:06 Q. Neovasc didn't invent that, did they?
A. I don't think so.
Q. You didn't invent it either, did you?
A. It's a claim there. I did not invent it. It's there. It's a prior -- it's an explanation.
Q. And why don't we take another example. Let's look at claim 27 toward the bottom.
"The method of Claim 1 further comprising reducing or eliminating mitral regurgitation." Well, that desire to reduce or eliminate mitral regurgitation, that's also something people
02:06 have known and wanted to do for a long time, correct?
A. Yes. Method of Claim 1, so it refers back to the claim of method, how do you reduce it.
Q. Not everything written in the claims of a patent is something new, correct?
A. No, it's not.

Q. Not everything written in the claims of a patent is an invention, correct?
A. No.
Q. You understand that anything that was already out there in the world published in the industry, even if it's included in the claims of a patent, that's just not an invention, correct?
A. That is correct.
MR. GRAVES: Thank you, Dr. Quadri. I have no further questions.
02:07 THE COURT: Redirect?
MR. GRAVES: Your Honor, before we do that, Your Honor, I'd like to put this back up with Dr. Quadri.
THE COURT: That's fine.
REDIRECT EXAMINATION BY MS. LEA:
Q. Now, Dr. Quadri, your published patents did not include your physical prototypes, did they?
A. No.
Q. And they didn't include your development history?
A. No.
02:08 Q. Now, did you disclose your method of anchoring at a conference?
A. No.
Q. Did anyone disclose that method on your behalf at a conference?
A. No.

Q. Did people come up to you and ask you about your method of anchoring at the conference?
A. Several times.
Q. And what was your response?
A. Well, just, it fixes, and I can't tell you how.
Q. Now, earlier we looked at -- my colleague brought up a photo in Exhibit 5004. Let's not put it up right now. This was the photo with the tiger stripes, as he referred to it.
A. Yes.
02:09 Q. Now, that photo did not actually show the CardiAQ device implanted in a heart, did it?
A. No.
Q. What did it show, in general? How did the device get there?
A. Well, if you look at that picture, it's just -- the heart is opened up, and the device is on top -- a portion of that picture shows outside the heart, a portion of the picture shows inside the heart. And there is a valve right on top of it, but it's really not where it ought to be.
02:10 Q. When was the device placed on the heart in that photo?
A. Just before taking the picture.
Q. Okay. So after the heart was opened up?
A. Yes.
Q. When it was outside --
A. Yes.

Q. -- of the study?
A. Yes.
Q. Not during the implantation?
A. No.
Q. Now, I would like to show you a photo from that same implantation. It's Exhibit 1458. Okay. We'll go ahead and publish this one. Do you recognize Exhibit 1458?
A. Yes.
Q. And is this a photo from the same implantation as Exhibit 5004?
A. That's correct.
Q. But there is a difference, right?
A. Yes.
Q. What's the difference?
A. There's a big difference. The implant is in the right location.
Q. So in Exhibit 1458 that we're showing now, the device was implanted --
A. Implanted in the mitral -- in the mitral annulus. So what we're seeing here is the heart is open here. You're looking from the bottom up into the ventricle, and there's a device, the prosthetic, the CardiAQ valve is here, part of it is visible here.
Q. And the device was implanted while the heart was beating?
A. Yes.

Q. Versus the Exhibit 5004 photo where the implant was placed on the heart after it had been removed?
A. Right.
Q. And was just simply cut open, and the device was set on top?
A. Right. They were trying to take pictures of different --
Q. Now, what can you tell here about the anchoring? Are there any anchors going between the chords?
A. This particular anchor is going to that chord, that chord, and there's a chord under there. Slides around there, tags the leaflet and sits right on the trigone.
Q. So that anchor is going between the chords around the leaflet and anchoring on the fibrous trigone portion of the annulus?
A. Yes, yes.
MS. LEA: You can take that down.
Q. Now, we heard testimony about a Dr. Virmani?
A. Right.
Q. Who hired Dr. Virmani?
A. Orbimed.
Q. And who is Orbimed?
A. Orbimed is a venture capital company based in New York City.
Q. And they were an investor in CardiAQ?
A. They were.

Q. Now, what did Orbimed do after receiving Dr. Virmani's opinions?
A. They invested in the company.
Q. How much did they invest?
A. About 20 million.
Q. $20 million?
A. Yes.
Q. Now, has there been -- other than back with Rev. C when we had the pinching and clamping, what happened after you did the
02:13 pinching and clamping? You went from Rev. C and did what?
A. We went from modified Rev. C, we went to Rev. D, we went to Rev. E, and then we did all kinds of changes from Rev. E to Rev. J, and then we implanted Rev. J in a human being.
Q. So Rev. D and E had a different type of anchoring than Rev. C?
A. Yes.
Q. What was the anchoring method for Rev. D and E?
A. D and E, the method was going behind the leaflet and capturing the leaflets, going between the chords and contacting
02:13 the annulus circumferentially.
Q. Did you carry that anchoring method through the further revisions?
A. Yes.
Q. Up to Rev. J?
A. Yes.

Q. That's all of Gen. 1?
A. Yes.
Q. And did you carry that anchoring method through to Gen. 2 as well?
A. Yes.
MS. LEA: I have no further questions.
THE COURT: Recross?
MR. GRAVES: No, Your Honor.
THE COURT: The witness may be excused. It's time for
02:14 your afternoon break. We'll see you back in about 15 minutes.
(Jury exits.)
THE COURT: Anything?
MR. GRAVES: We should probably speak about sequestration of witnesses after testimony is over. We don't know whether the plaintiffs are planning, for example, rebuttal or things like that, and that raises some concern about sequestration.
MS. LEA: We don't plan to call Dr. Quadri on rebuttal, Your Honor.
02:15 THE COURT: Okay. As long as the witness is not going to be called on rebuttal, there's no need for continuing sequestration as far as I'm concerned.
MS. LEA: We agree.
THE COURT: All right.
MS. LEA: Would you like to do the exhibits now or at

the end of the day?

THE COURT: If you guys want a break, I want to let you have the break. But if you don't care, I'm just as happy to do it now.

MS. LEA: Why don't we do at the end of the day.

MR. GRAVES: Yes, let's get our team to get them together.

THE COURT: We need to take a little bit of break to switch reporters. Other than that, I'm happy to use these 15 minutes to work or not work, whatever you all want to do. End of the day?

02:16

MS. LEA: Yes.

THE COURT: That's fine.

(Recess taken, 2:15 p.m.)

(Resumed, 2:32 p.m.)

(Jury enters the courtroom.)

THE COURT: You may call your next witness.

MR. SGANGA: Thank you, your Honor. The plaintiff calls Mr. Brent Ratz as its next witness.

02:32

JEREMY BRENT RATZ

having been first duly sworn, was examined and testified as follows:

THE CLERK: Can you please state your name and spell your last name for the record.

THE WITNESS: My full name is Jeremy Brent Ratz. Last

name is R-a-t-z.

DIRECT EXAMINATION BY MR. SGANGA:

Q. Good afternoon, Mr. Ratz.

A. Good afternoon.

Q. Can you tell us your current profession, please.

A. I'm currently Vice President of Research and Development for Edwards Lifesciences in their Transcatheter Mitral Valve Replacement Group.

Q. And do you have any professional background as an

02:33 engineer?

A. I do. I went to undergrad for biomedical engineering at Duke University.

Q. And for how long have you been working as a medical device engineer?

A. I've been in the industry for I guess about fifteen years now, and spent almost all that time on the engineering side.

Q. You mentioned you have a degree in biomedical engineering undergraduate. Do you have any other college degrees?

A. I have an MBA from the Wharton School, the University of

02:34 Pennsylvania.

Q. Can you tell me about your work experience as a biomedical engineer, starting with the first full-time job you had.

A. Sure. So while I was still in college, I did two summer internships with a company called UTI Corporation. They did contract development, contract manufacturing for the medical

device industry. I spent a year after graduation working in Boston as a management consultant, but shortly after that went back to UTI Corporation for another six and a half years to work in project engineering.

Q. And UTI then changed its name to Accellent at some point?

A. It did. In 2004 it acquired another company and changed its name to Accellent.

Q. And you mentioned that they were in the business of contract manufacturing. Can you explain what that is.

02:34 A. Right, so they provided outsource services to the medical device industry. They essentially functioned as an extension of -- or we functioned as an extension of our customers, so from the R&D side doing design and development, all the way through manufacturing of finished packaged goods and subassemblies and components, so really a one-stop shop for medical device companies.

Q. So why would a medical device company go to Accellent and use them as a contractor as opposed to just making the products themselves?

02:35 A. Well, there's a lot of different types of customers that we had, so it ranged from small start-ups where it might be a small team that didn't have the capabilities to perform those resources in-house, all the way to multinational companies like J&J or Boston Scientific/Medtronic that wanted to use us as an extension of their own in-house resources. Sometimes it was

because we had specialized skills. Sometimes it was just because they had a new program or wanted to offset resources or have a way to have variable costs instead of fixed costs and expanding their manufacturing themselves.

Q. Can you just tell us briefly what your job responsibilities were at Accellent.

A. When I started there, I was a project engineer, and so I was responsible for a few programs myself, mostly in the development and prototyping side. I stayed with the company through the transition to Accellent when they made that acquisition; and then my role grew to being responsible for a number of other project managers, all of whom were kind of functioning as an extension of our customers' R&D teams to take either prototypes or to take whole programs through all phases of design and development. In the later portion, I was group manager of program management, and then in my final year there, I was a field sales engineer and kind of shifted out to selling the services to our customers.

Q. So what kind of medical devices did you work with while you were at Accellent?

A. I got to work on a little bit of everything, so ranging from cardiovascular to orthopedic to endoscopy to breast biopsy devices, really across the board.

Q. Can you tell us how you met Dr. Quadri.

A. I met Dr. Quadri through a business school classmate. He

went to school with me at Wharton, but he was from Hartford, Connecticut. And he called me up in the summer of 2006 and said, "Hey, my next-door neighbor is a cardiac surgeon. He's got this crazy idea for a heart valve. Do you think you could help him out?" And that was in July of '06, and then I think I first met Dr. Quadri in August, '06, face-to-face.

Q. And after you met, did you start working together?

A. We did. We started working together immediately. He became a customer of Accellent. I had just transitioned to the

02:37 sales side, but because it was sort of a new, you know, small opportunity and I had come from the program management side, I was kind of managing it myself as well on the R&D front.

Q. Were you spending any of your spare time helping Dr. Quadri when you first started working with him?

A. I was, a lot of spare time. So kind of nights and weekends became supporting this project and sort of seeing, you know, what the opportunity might look like, working with Dr. Quadri to kind of put together the financial model and the business plan. I had focused on entrepreneurship at Wharton,

02:38 and so I was kind of excited to sort of, you know, cut my teeth on this a little bit, and it was a good fit of, you know, what my background was.

Q. Did there come a time when you left Accellent to join CardiAQ full time?

A. I did. Dr. Quadri asked me sometime during the course of

late 2006, early 2007 to come on as CEO, and I said, "Do we need to raise some money first?" And so he had put a lot of money in himself, I put some of my own money in, and we scraped enough money from friends and family that by October of '07 I could quit my day job and focus on CardiAQ full time.

Q. So how did you feel about leaving a steady day job.

A. It was a big decision. It was a big decision for me and for my family. I had two young kids at that time under the age of two, I had a mortgage, so, you know, leaving a steady job

02:38 with a nice trajectory was a big choice to make. But for me, I always wanted to do something entrepreneurial. It was sort of this perfect combination of the medical side and the business side, and this, you know, opportunity to kind of create something new. And really from, you know, seven years with contract manufacturing, it was an opportunity for me to do something that was focused on the patients and got me closer to kind of what was going on, you know, in the clinical environment.

Q. So how many employees did CardiAQ have when you joined in

02:39 2007?

A. Just one. It was me.

Q. And what about Dr. Quadri?

A. He was a consultant, as he mentioned earlier.

Q. And your title you said, was it CEO?

A. President and CEO in a company of one.

Q. I'm sorry?
A. I just said "in a company of one."
Q. Did you make any changes to the corporate structure of CardiAQ after you joined it?
A. We did. So shortly after I joined full time, in mid-November, '07, we shifted from CardiAQ, LLC to CardiAQ Valve Technologies, Inc. We converted it to a C corporation, really just to facilitate venture capital investment, or in the hopes of attracting venture capital investment.
02:40 Q. And where were the company's offices?
A. At my home in Winchester, Massachusetts.
Q. And from there, were you handling all the company finances?
A. I was doing everything.
Q. And where were your lawyers located?
A. We had corporate counsel just outside of Boston in Waltham.
Q. So if you didn't have employees, what were you planning to do in order to actually make the medical devices that CardiAQ
02:40 was going to work on?
A. So we knew that we were going to be designing ourselves just between Dr. Quadri and I; but having spent basically seven years in contract manufacturing, I was very comfortable with the idea of outsourcing the things that we couldn't do in-house to have it manufactured by, you know, other vendors that were

much more capable, had many more resources than we could hope to kind of build internally at the time.
Q. So what made you comfortable that you could trust vendors with the technology that CardiAQ was working on?
A. In the same way that, you know, all of our customers at Accellent had trusted us; in the same way that Accellent had used subcontractors ourselves, we trusted them. We had NDAs in place. We used those throughout our relationships at Accellent, again, with our own subcontractors there, and then
02:41 once we were with CardiAQ, we did the same.
Q. Now, who owned the technology that CardiAQ was developing for its heart valve designs?
A. It was all owned by the company. Even when we first started, the patents that were in Dr. Quadri's name we had transferred over to the company.
Q. Okay, and were there assignment agreements to that effect?
A. There were.
Q. Do you have in your binder Exhibit 1327?
A. Yes, I do.
02:42 Q. Can you tell us what that document is.
A. This is a technology assignment agreement between the company and Dr. Quadri that was entered into on January 9, 2008.
Q. And the purpose of this agreement?
A. The purpose of this agreement was to set the stage for

future assignments of technology, and also to assign over the initial patents that he had in his name that were relevant to what we were doing.

Q. How about you, did you have an assignment agreement to assign your ideas to CardiAQ?

A. I did. I had an employment agreement with an invention assignment attachment to that.

Q. Okay, could you turn to Exhibit 1356, please. Can you tell us what this exhibit is.

02:42 A. This is my employment agreement entered into in early January, '08. If you flip to the back of that, there's a Propriety Information and Inventions Agreement that governs the ownership of any IP that's created during the course of the employment.

Q. And when you say IP, is that the initials for intellectual property?

A. Intellectual property, yes.

Q. And so that would include any trade secrets?

A. Correct.

02:43 Q. And then if you turn to Exhibit 1432, can you tell us what that document is.

A. This is a consulting agreement with Q Ventures LLC, which is the company that Dr. Quadri had set up just for managing his consulting.

Q. And as part of the consulting agreement, did this assign

the intellectual property rights to the company?
A. It does, Clause No. 2 there, the ownership rights, proprietary information.
Q. When CardiAQ started hiring employees later on down the road, what did you do, if anything, to have the ideas that those employees came up with be owned by the company?
A. We took the same steps as we did in my employment agreement to have that invention assignment attachment to it, and so everyone that was hired on as an employee signed that.
02:44 Q. So let's talk about the finances of the company. How was the company funded when you joined?
A. As I mentioned, all friends and family investments, so just small angel investors; you know, a long list of people that contributed little bits at a time to kind of add up to enough to get us off the ground.
Q. And so there were no sales of any products yet by CardiAQ, right?
A. No.
Q. What was the focus of the company when you joined?
02:44 A. When I joined initially in 2007, we had already kind of earlier that year shifted our focus to this concept for rapid fixation aortic valve replacement. The idea was, we kind of knew that with what Dr. Quadri initially came to us with at Accellent for this transcatheter idea for aortic valve replacement, that we were going to be two or three generations

behind the leaders in that field, some of whom had already gotten approval to market their devices in Europe by 2007. And we said, in order for us to kind of move forward, we need to find a niche opportunity where we can, you know, be first or differentiate ourselves; and this idea came up for rapid fixation aortic valve replacement where you could replace a person's aortic valve, again, the one that's calcified, this valve here with the calcified leaflets. And the thought was, if you just pop another valve in there on top of the
02:45 calcification, you may get leaks, it might not be as perfect as you would otherwise if you could remove that; but if you could go in with a small incision, surgically excise or remove those calcified leaflets, quickly pop in another valve on a frame like the one that we've seen earlier, you could do that with much less time on bypass and have this be much, much safer for the patients, even though it still was a minimally invasive surgical procedure.

Q. So what kind of reaction did you get from potential investors about this rapid fixation aortic valve device?

02:46 A. It was a kind "Thanks but no thanks." I think it was, you know, regarded as something that might be of value but not something that would warrant a stand-alone company, just too small of an opportunity. So it was kind of a, you know, sort of no-man's-land in the end between the tried-and-true surgical aortic valve technologies and what was kind of the hot new

space of transcatheter aortic valve replacement.
Q. So what did you do next?
A. Well, we had always kind of spoken to potential investors about this being a platform technology that could apply to multiple areas within the heart, even beyond maybe, but within the heart, you know, we had said maybe it could also be applied to mitral as well, and we started to look more at the mitral opportunity. People started to ask us to tell us more about what you could do on the mitral side. And it was around that
02:46 same time in the summer of 2008, we started to see what was going on in the mitral space with companies that were trying to repair the mitral valve via catheter, via this less-invasive approach, and those companies weren't really showing any clinical efficacy. And we looked at our technology and we said: We've got a technology that can go in the mitral space where nobody else can. None of the repair technologies are working particularly well. None of the aortic technologies can transfer over to the mitral, and so at that point we shifted our focus.
02:47 Q. So you were talking about transferring your technology from the aortic to the mitral. Did you have an expectation that you could literally take rapid fixation aortic device and plop it in a mitral valve?
A. No. We knew -- again, we thought it was a platform technology that could be leveraged, but we knew that there was

going to be a lot of work to do to go from the aortic side to the mitral side. And you've heard a lot already about it's just such a different animal from an anatomical standpoint, and there's so many other challenges and considerations, so we knew that we had a long road ahead of us.

Q. Did you have any understanding as to how big the need was for a minimally invasive mitral valve replacement?

A. We did. So when we took that summer to kind of go through the opportunity on the mitral side and saw where, you know, others weren't able to achieve what we were hoping to achieve, we took a hard look at the market opportunity, the unmet clinical need. I think somebody mentioned already, but, you know, there were four million people suffering from MR. Only a subset of those patients get treated every year, so there are estimated about 80,000 out of four million that have severe symptomatic MR that actually get definitive surgery through repair replacement; and of those people that are severe symptomatic, about fifty percent or more as you go into, you know, older age groups are not referred for surgery because of how invasive it is. So we knew that it was a huge opportunity, even bigger than the number of patients that weren't treated on the aortic side.

Q. So did you have an estimate of the number of patients each year who had severe MR but couldn't get any kind of treatment?

A. Yeah, I think at the time the estimate was that there is

at least 80,000 additional patients that could be treated; there's another, you know, 200,000 of new patients that are diagnosed with MR each year, so it's a growing year.

Q. So were there other companies that were trying to come up with a transcatheter mitral valve replacement at this time in 2008?

A. Nobody else at the time that had anything that was in humans, had anything that was approved obviously. There were only two other companies at the time that we knew of. One was

02:49 actually a company, and one was just a professor in Germany that was working on kind of his own concept, Endovalve and a gentleman named George Leuter, who is a cardiac surgeon in Germany.

Q. So you knew you'd be competing with them, right?

A. We knew there were other competitors.

Q. What about the big medical device companies that were already successful with the transcatheter aortic valve products, what was your understanding of their efforts in this transcatheter mitral valve space?

02:50 A. Presumably they were interested. Some of them had publicized transcatheter mitral repair programs. Nobody at that point had publicized an internal transcatheter mitral replacement program, but we obviously suspected that it was something that they may be working on behind closed doors, or, you know, something that they may be interested in for sure.

Q. Did you have any beliefs as to why no one had been able to successfully come up with a transcatheter mitral valve device yet?
A. We certainly knew what the challenges were, so that much was clear. In terms of why it was different, I think, you know, early on people thought that mitral repair would get to market first. It was more of a direct kind of conversion from what surgery was doing as the gold standard, so less people were thinking about mitral replacement transcatheter; and I
02:50 think everybody was really at that point focused on the rapid progress that was being made for transcatheter aortic valve replacement, and so they were kind of putting lot of their energy in there. But it was clear that the transcatheter aortic valves were not going to work in the mitral position. Otherwise, these companies that were much bigger, much further ahead there, would have just taken their valve and put it on the other side of the heart, the other side of the ventricle.
Q. And did you have an understanding what the differences were anatomically that made the mitral valve more of a
02:51 challenge?
A. Sure. You know, we've heard about some of it. I'll talk about it a little bit, but, you know, it's a much bigger valve just by comparison. You know, roughly, it's probably twice the cross-sectional area of the aortic valve. You've got the higher pressure, so, again, the systolic pressure, which is

sort of the 120 in your 120 over 80, and the diastolic is the 80, so the 80 is closing the aortic. The 120 or more in these high blood pressure patients is closing the mitral. So just, you know, some rough engineering, if you've got higher pressure and bigger area, you've got much higher forces than anything that you'd see on the aortic side, and then you've got the absence of this calcification, so it's smooth tissue by and large that you're trying to attach to. So as we've talked about already, you can't just sort of push out on these
02:52 calcified leaflets and get a foothold to try to hold the valve in place. On the aortic side, you've got this cylindrical conduit, so you can have a lot of surface area to push up against. On the mitral side, you've got open cavities above and below, so you've really just got this thin ledge of the annulus to try to use to position your device and also get it to hold in place. And then of course you've got the dynamic aspects of the valve with the leaflets moving into the chordae and then the papillary muscles. And as Dr. Quadri talked about already, we want to try to preserve all that; that's what keeps
02:52 the ventricle functioning properly. So there's all these considerations.

You want to make sure -- you know, he talked about SAM or systolic anterior leaflet motion. You don't want this anterior leaflet to get blocked or pushed out into the way of the outflow track here because that will serve to block blood

flowing out of the heart. So there's a lot going on in the mitral side compared to this kind of this, you know, passive aspect of the aortic side.

Q. So when you decided to make the shift to work on a mitral valve in 2008, what, if anything, did you do to educate yourself about all the anatomy that you just told us about?

A. I read a lot of papers. You know, some of the conferences in the industry have come up. We attended a lot of conferences. I attended a lot of mitral sessions at those conferences. Even sort of just after we decided to go mitral, we attended the European Association of Cardiothoracic Surgery Conference in Portugal that year, September of '08, I believe it was. So we're sitting in on these conferences. And then, you know, I've got the luxury of Dr. Quadri kind of as my personal medical professor to educate me. So not everybody has a cardiac surgeon, you know, as a partner, but he obviously taught me a lot about the mitral anatomy.

Q. Did you ever learn about that part of the mitral valve anatomy called the fibrous trigones?

A. I did.

Q. And do you remember talking with Dr. Quadri about it?

A. I do.

Q. And if you turn to Exhibit 1411 in your book, can you tell us what this document is.

A. This is a page from one of my notebooks that I, you know,

kept roughly daily, just kind of detailing everything that was going on in the company, everything that I sort of did each day or what I in this case had to do each day, and, you know, kind of a checklist here.

Q. And was this all entries that you made personally?

A. Yes.

Q. And when you filled out the notebooks, filled up all the pages, what did you do with them?

A. I just moved on to another one.

02:54 Q. And you saved all those, obviously?

A. Yes.

Q. Okay. So in Exhibit 1411, if we could turn to Page No. 41 of 167, which is up on the screen, there's a sketch in the lower right-hand corner. Did you draw that?

A. I did.

Q. And what's the word written in the bottom right corner there?

A. "Trigone."

Q. And can you describe what that is pointing to, that arrow?

02:55 A. It's pointing to the two dark spots on either side of the sort of dotted line that represents the mitral annulus. The kind of dark smiley face in between there is a coaptation of the mitral leaflets.

Q. Do you have the laser? Yes. So the mitral valve is which?

A. So here's the Trigone 1, Trigone 2. This is the fibrous region in between. This is the aortic valve here, mitral valve here, and then you've got the coronaries here on either side. And this was really just, you know, from a discussion with Dr. Quadri, I think it was a sidebar at that EX conference just going through this stuff but obviously noted at the time. And this is when we were first starting to think about mitral, and so we were considering all the aspects of the anatomy.

Q. And if you could just tell us what the date is on this page where you made the sketch.

A. It's not on there. We might have to look at the page before, the page before that.

Q. Okay, well, we'll move ahead there. But --

A. But I believe it's from that conference. The rest of the notes are representative of notes I was taking from other presentations there.

Q. And that was in September of 2008?

A. Correct.

Q. So did you have an understanding then as to what the relationship was between the trigones and the mitral annulus?

A. Yes. You know, I knew that it was part of the annulus. We talked about the fact that, you know, roughly two-fifths of the circumference of the mitral valve made up that fibrous trigone-to-trigone region. The other three-fifths on the posterior side here on kind of the back wall was the more

compliant region.
Q. So we've been talking a lot about trigones here and talking about whether you've got other documents referring to trigones. Are there many other documents that you generated working at CardiAQ referring to trigones specifically?
A. No. I think there's a couple other sketches early on here where we point it out, but, no, after that, we understood it as part of the annulus. You know, I was clear on it from my discussions with Dr. Quadri, and so it wasn't something that
02:57 continued to show up in my notes really after that.
Q. Did you typically label every anatomical feature when you drew a sketch of something around the mitral valve?
A. No, I did not.
Q. So let's talk about the design work on CardiAQ's transcatheter mitral valve designs. And TMVI, is that the acronym?
A. TMVI or TMVR, so replacement or implantation I guess kind of started to get used interchangeably.
Q. Okay, so when did you start working on your TMVI designs?
02:58 A. We really started on it that fall. You know, in August of '08, I think we were already sketching some things, and then, you know, kind of making that more detailed, more refined throughout the next couple months.
Q. Did you have a name or revision number for this design?
A. We started with Revision A.

Q. And prior to that, those rapid fixation aortic --
A. We had been on kind of a numeric revision schedule, so we went 1, 2, 3, 4 on the rapid fixation, and when we went mitral, we started alphabetic.
Q. So if you could look at Exhibit 1407, please. Is this another one of your lab notebooks?
A. Yes.
Q. And if you could turn to Page 15. We'll pull that up on the screen as well. And can you tell us what the sketch is at
02:58 the bottom of the page, please.
A. This is one of the original sketches of what was Revision A from a brainstorming conversation with Q. That's what I called Dr. Quadri. And you see, you know, the rough idea of having this shoulder on the atrial side having these curved ventricular anchors, and the concepts that are kind of written down there just defining a few things about it.
Q. And what were you intending as far as how this Rev. A design would anchor in place inside the heart?
A. As we talked about before, it was at this point still this
02:59 idea of clamping onto the annulus, pinching the leaflets in between here so that the bulge could kind of push the leaflet aside and create more of a ledge here that we could pinch onto the annulus.
Q. And the date on this one, is that up in the right-hand corner there?

A. December 30, 2008.
Q. So what happened to the Rev. A design?
A. You know, we continued to kind of brainstorm and think about what we needed there, and, you know, I guess the biggest shift from A to B was really just thinking that we needed a skirt along the bottom there before we moved forward. So we never actually made any prototypes of Rev. A. We did some, you know, detailed drawings, or I did some detailed drawings of it, but --
03:00 Q. And did you analyze the design from an engineering perspective?
A. We did a little bit. We did more of that with Rev. B, I think, but, you know, we started looking at finite element analysis to kind of understand how the material would behave.
Q. Can you explain what that is, finite element analysis.
A. Finite element analysis is where you sort of take a design for a metal frame, or it could be any, you know, component really, and you just understand the stresses that it might see as you put a load on one side of it. So there's various ways
03:00 to use it, but it basically breaks down the larger structure into tiny, tiny little elements, finite elements that you can look at and then analyze each one independently, and then get kind of an overall idea of how much strain it may see, which was really important, given the materials that we were using.
Q. And that's done with computer software?

A. It is.
Q. So let's talk about the next revision. I think you said that was Rev. B. And can you explain how you were intending the Rev. B device to anchor?
A. So Rev. B was intended to anchor in the same way, by sort of pushing the native leaflets aside intra-annularly and creating this ledge to kind of pinch onto above and below the native annulus.
Q. Okay, if we could put up PDX 3.2. Can you explain what
03:01 we're seeing here?
A. Yes. We're seeing the idea for the, you know, the clamping action still where we've just sort of pushed the native leaflets aside and created, you know, more of this ledge to kind of pinch onto here. The idea was that this extra little gusset or skirt would create more leak prevention than we had in the Rev. A where there was no coverage there at the time.
Q. And were there other changes that you made between Rev. A and Rev. B?
03:02 A. We experimented a little bit with the valve location in Rev. B, so we looked at opportunities for it to be kind of higher or lower, you know, intra-annular or sub-annular even, and, you know, looked at modifications that way.
Q. If we look at the two revs side by side here, can you tell us, is that an accurate representation of the Rev. A and Rev. B

designs?
A. It is. Yeah, we had a number of different variations of B, so this looks like what we were kind of referring to as B-1. You can see we positioned it a little bit lower on the left atrial side here just to try to reduce the valve height. We changed from this kind of pronounced ledge here to this, you know, just transition shelf flange kind of flared-out region. We actually had the fabric kind of on the outside of the frame here and we had that on the inside of the frame here to be
03:03 consistent with where the valve was located and to kind of wrap this around. And, you know, one of the ideas behind going from this sort of pronounced ledge to the transition here was just to minimize the length of material it took to sort of walk that path from the inside to the outside because that had implications for, once you compress it, how long it is as it extends out and how long it is in the delivery system.
Q. And were you doing all of the design and engineering work for Revs. A and B?
A. I was. So I was doing the, you know, the CAD drawings, or
03:03 computer assisted drafting, all the detailed designs, all the sketches, all the three-dimensional designs, flat patterns.
Q. And were any prototypes made of the Rev. B design?
A. We made a prototype of the Rev. B frame, the one that you see on the screen here right now.
Q. And what did you do with that prototype frame?

A. We evaluated it in terms of compressibility. We evaluated it just by hand to kind of assess. We may have put it in sort of a, you know, a mock kind of silicone annulus just to kind of pull on it a little bit and see how the anchors deflected. But, you know, we could learn a lot just from holding it in our hands and kind of squeezing it and feeling the resistance, you know, what it might see inside the native environment.

Q. And how were you funding the company at the time you were working on Rev. B?

03:04 A. At the time we were working on Rev. B, we really didn't have any money left. We had raised about $650,000 when I first joined the company and, you know, spent almost all of that. So the Rev. B time frame was kind of early 2009. I had gone about five months without a salary before we got our next round of funding, so it was sort of a dicey time for the company. You know, we were kind of getting a lot of pressure to think about contingency plans, and we had the potential to close some funding with a Boston-based VC, but it hadn't happened yet, so we were still kind of looking for all opportunities to raise

03:05 more funds.

Q. So were you still working full time, though, throughout this period?

A. Still working full time.

Q. Did you have a strategy to raise some more money?

A. We did. I mean, our objective at this point was really to

get the message out there. You know, we didn't have enough money. We didn't have the design far enough along yet to do animal studies to kind of convince people. A lot of venture capitalists want to see at least successful animals before they'll turn over a lot of money to you. So we had to really just tell the story. We had to sort of, you know, put the images in the presentation and, you know, kind of convince people of the promise of this.

Q. So were there details, engineering details about the designs that you left out of presentations to potential investors?

A. We did, and we never showed detailed dimensional drawings to potential investors, you know, or engineering prints or anything like that. We were showing, you know, images, illustrations like this, you know, screenshots maybe or pictures, but not any detailed information.

Q. Were you handing out prototypes?

A. No.

Q. So at some point, though, did you actually post information about the Rev. B design frame online?

A. I did.

Q. And can you explain why you did that.

A. Yeah, so in the opening statements, you guys saw some of the, you know, fancy animations of, you know, cartoons and movies of how these devices work. We didn't really have the

money to put one of those together at the time, but I thought it would be meaningful to try to communicate to potential investors how we could do that. I took out a 30-day free trial of this Autodesk software called 3ds Max and started to try to make my own animation from the information that we had. At one point in that process, I was kind of hitting a wall, and so I posted some information about the Rev. B design on one of their advice forums to try to solicit some feedback from some professionals in that area to guide my animation skills.

03:07 Q. Did you ever post designs online like that for any of the later revisions to your designs after Rev. B?

A. No, never.

Q. And how did the Rev. B compare to the later designs that you ended up working on with Neovasc?

A. It was really quite different, you know, from a number of aspects.

Q. Was the first design that you had Neovasc help assemble the Rev. C prototype?

A. That's correct.

03:07 Q. So if we could pull up a Rev. C prototype here next, the next version. Can you tell us how the Rev. C design differed from Rev. B.

A. Sure. So we made a number of changes. Starting at the top, I guess this is where we had added the mushroom-shaped tabs for the locking feature connection to the delivery system.

We had eyelets there before. We went from nine cells to twelve cells, and by "cells," I just mean the sort of symmetric section that repeats around the circumference of the frame. So this one had nine. We went to twelve here, mainly because we wanted to be able to compress it more easily. So you can see with nine trying to reach a larger diameter, you could get a very wide angle here. With twelve trying to reach a smaller diameter, you get a narrower angle here. It makes it easier to compress the valve for loading into a catheter, and that was, again, what we were focused on here.

03:08

We got rid of the shelf here. We thought that we were going to need more contact with the left atrial side of the annulus, and so we substituted the shelf. Again, this sort of takes this pathway that makes it longer when you compress it for these V-shaped anchors that could be cut from inside the frame and wouldn't cost us anything in terms of additional length of the device when we put it into the catheter.

And then you can see we made modifications to the base here. To cover these anchors fully, you know, as we thought about it more and this idea that we were going to be inside the native annulus and pushing these leaflets aside, we didn't want to have a leak path around there, so we thought it was important for that coverage to go all the way to the top. It also gave us a way to kind of have this clamping action sort of continue even in that intra-anchor space there where we didn't

03:09

have one of the twelve anchors directly under it.
Q. So when did you start working on that Rev. C design?
A. I started sketching it in my notebook around April, 2010.
Q. And when did you start working with Neovasc? Do you recall?
A. It was early June, 2009.
Q. So how did you come about getting in contact with Neovasc?
A. We received an unsolicited e-mail from Mr. Brian McPherson.
03:10 Q. And what's his position at Neovasc?
A. I forget the exact title. I think he was in charge of business development, though.
Q. So can you look at Exhibit 349 in your notebook, please. Can you identify that for us.
A. This is an e-mail from Mr. McPherson to me.
Q. Is this the first contact you ever had with anyone at Neovasc?
A. Yes, it is.
Q. And can you tell us when this was sent?
03:10 A. It was sent on June 4, 2009.
Q. And you were working out of your home in Massachusetts still when you received this?
A. That's correct.
Q. Okay. And was there an attachment to the e-mail?
A. There was. He had attached an introductory PowerPoint

presentation of the Neovasc company and their services.
Q. And did you review that attachment when you received it in June, '09?
A. I did.
Q. So I'd like to direct you to Page 4 of 16 in Exhibit 349. And what did you understand from the first bullet point listed there?
A. You know, mainly that they treated their customers as partners, is how I understood that: "Our customers are
03:11 typically industry partners who incorporate Neovasc pericardial tissue materials into their own products."
Q. And did you read the second bullet point as well?
A. I did. It, you know, just talked about their areas of specialization, but mainly that they were tissue providers, as I understood it.
Q. And I also just want to point you to the fourth bullet point there. Okay, no, sorry. If you'd turn to -- we're still on Page 3 here, and there's a reference to...
Did you get any understanding from them as to any other
03:12 products besides tissue products that Neovasc was working on at the time?
A. Mr. McPherson mentioned in his e-mail that they had the Neovasc reducer program, and I think it mentioned in the presentation that it was a device for treating refractory angina.

Q. And if we turn to Page No. 6 of 16, is there a reference to that?

(Witness examining document.)

Q. Sorry about this. I've got the pages off-track here. And when Neovasc contacted you, did they give you any indication that they were working on developing or planning to develop any of their own heart valves?

A. No.

Q. So let's go back to Page No. 3 of the slide deck here. Is there a reference to their core products there?

A. Again, that they were focused on pericardial tissue and then the reducer stent for refractory angina that we --

Q. That you mentioned. And the reducer stent, did you think that had anything to do with valve technology?

A. No.

Q. Did you have any idea that Neovasc was planning to start designing any of its own transcatheter heart valve products?

A. No.

MR. FLYNN: Objection, lacks foundation, calls for speculation.

THE COURT: Sorry. I can't hear you.

MR. FLYNN: Lacks foundation, calls for speculation.

THE COURT: Overruled.

Q. In addition to the e-mail that you received from Mr. McPherson at Neovasc, did you speak with anyone at Neovasc

as a result of this initial contact?
A. I had not spoken to anybody at that point, but we, you know, quickly exchanged e-mails, and I made an attempt to set up an initial call.
Q. If you had learned any information from Neovasc that it had planned to develop its own mitral valve product, how would that have impacted your willingness to work with Neovasc as a contract manufacturer?
A. We would have had serious concerns. It's highly unlikely
03:14 that we would have proceeded to work with them.
Q. How was the timing of the e-mail with respect to your need to assemble prototypes?
A. It was close to perfect. We were sort of getting ready with the Rev. C and wanted to head into animal studies later that summer, so -- and I think we saw that e-mail to Dr. Quadri earlier, but it seemed like a good fit.
Q. So you said you were going without a paycheck for a while, right? How were you planning on paying Neovasc to do the services?
03:15 A. So thankfully we finally raised some money in May of 2009, so we had just brought in about another $800,000, including some money from that venture capitalist in the Boston area.
Q. So you had some more money. Why didn't you just keep doing the prototyping yourself at CardiAQ?
A. A couple reasons. You know, I think we had done animal

studies before with valves that Dr. Quadri had hand made, and so we certainly could have proceeded down that path, at least to do some short-term animal studies. But in order to ultimately do chronic animal studies, we would need to be able to assemble those valves in a clean room environment, in a sterile environment, and have those valves sterilized; and we didn't have the wherewithal to do that ourselves, so we would have had to start hiring people. But at the same time, you know, Dr. Quadri is a practicing cardiac surgeon. You know, it's probably not ultimately long term the best use of his time to be assembling these valves by hand. So naturally, you know, we kind of perked up when we saw that there is a contract manufacturer that could do exactly that for us.

Q. Now, did Neovasc have any of its own unique technology relating to the tissue business that you wanted to take advantage of?

A. Nothing that we wanted to take advantage of. We really just needed, you know, standard glutaraldehyde-fixed pericardial tissue. They had technology that they discussed with us called Geoform, which was to make sort of three-dimensional fixed shapes out of tissue, but that was not something that was of any value to us.

Q. Now, before you started sharing any of the designs for CardiAQ's TMVI products with Neovasc, did you take any steps to protect the confidentiality of that information?

A. I did. So before I started sending any information to them, I sent an e-mail to Mr. McPherson requesting that he sign a copy of CardiAQ's NDA.
Q. And what happened after you made that request?
A. He replied that he would prefer to use Neovasc's own template for an NDA and provided me with a copy of that for review.
Q. And did you end up signing the NDA that was proposed by Neovasc?
03:17 A. I did. I reviewed that NDA and looked at it next to ours and felt comfortable with it and signed the NDA.
Q. So if you turn to Exhibit 371, is that the signed nondisclosure agreement, or NDA, between CardiAQ and Neovasc?
A. Yes, it is.
Q. Now, you've mentioned that you thought it would help protect CardiAQ's technology. Was there anything that you saw in the agreement that gave you comfort that it would protect the designs that you were working on?
A. I did several things, but I guess first and foremost was
03:18 Item 1 in the definition of confidential information, which I felt broadly covered the information that we would anticipate sharing with Neovasc over the course of any relationship.
Q. And what kinds of things were you thinking that you would disclose to Neovasc so that they could assemble prototypes for you?

A. Really, you know, exactly as it's listed here. So "Confidential information included, by way of example and not limitation, information of a technical nature such as trade secrets, manufacturing processes or devices, current products or products under development, research subjects, methods and results, matters of a business nature such as information about costs, margins, pricing, policies, et cetera, marketing or strategic plans, financial information, personal records or other information of a similar nature." So it seemed
03:19 sufficiently broad to me to cover anything and everything that we might have reason to share with them.
Q. Did the NDA include any restrictions on what Neovasc could do with your confidential information that made you comfortable sharing it with them?
A. It did. You know, Item 3 talks about how that confidential information can be used, and specifically just the last portion there, "The recipient shall not directly or indirectly disclose any confidential information to any third party or use the confidential information for its own benefit
03:20 or for the benefit of any third party."
Q. And how did you think that impacted Neovasc, if at all, if they were going to be working themselves on a competing TMVI device?
A. You know, our intent was not to prevent anybody from competing, and we certainly didn't expect that this company

that positioned themselves as a partner would become a competitor, but we weren't in the business of trying to, you know, prevent anybody from entering the field. We simply just wanted to make sure that our confidential information was protected.

Q. So how important did you think this provision in Section 3 about Neovasc not using the confidential information for its own benefit was?

A. It's very important. I mean, that's really, you know, the primary reason for having this document in place.

Q. And was there anything that you saw in the Neovasc form nondisclosure agreement that mentioned licensing your intellectual property to Neovasc?

A. There was a clause that just made it clear that -- I think No. 6 on the backside there -- that this document or furnishing any confidential information shall not constitute or be construed as a grant of any express or implied license or other right. So it was, you know, clear that we weren't granting them any special rights to use our information just by providing it.

Q. Did you consider that important when you were deciding whether to enter the relationship with Neovasc?

A. Absolutely. You know, our strategy as a company at that point was, and always was, to develop our own device. We weren't, you know, in the business of trying to come up with

intellectual property that we would license off or try to get royalties from, you know, other medical device players.
Q. Did you see anything in the NDA mentioning how Neovasc needed to take efforts to safeguard the confidentiality of your technology, in Section 2 perhaps?
A. I think just the idea that they would treat it as they would treat their own confidential information.
Q. And did you have any understanding as to what the NDA would allow Neovasc to do in terms of independently developing
03:22 any of its own TMVI devices?
A. I did. That was covered in Section 4. You know, so certainly to the extent that any information was already known or became public knowledge, was disclosed by a third party without restriction, or independently developed by the recipient, as long as it was without resort to the disclosure, or, you know, without using our confidential information again.
Q. And how important did you consider that in deciding whether you were comfortable sharing CardiAQ's prototypes with Neovasc?
03:23 A. It was very important to us. And, like I said, you know, we did not want to prevent competition. We just wanted to make sure that our information was not misused or used for anybody else's benefit.
Q. Now, had you had prior experiences with nondisclosure agreements at Accellent?

A. I had. We routinely had them in place with all of our customers. We had them in place with the subcontractors that we worked with. You know, there were a lot of things that we couldn't do in-house at Accellent, and so we used other vendors to make those subassemblies for us, and we would have NDAs in place with them as well, just to make sure everything was safeguarded.

Q. So did you have any experience where Accellent as a contract manufacturer decided it wanted to go into competition with one of its customers?

03:23

A. No.

Q. Did you ever have an experience at CardiAQ where any other vendors or contract manufacturers of CardiAQ's was interested in doing something that was competing with CardiAQ?

A. We did actually. In the summer of 2009, the person that was making our nitinol frames for us, the metal frames for our implant, approached us and said he had his own idea for a mitral valve implant and wanted to show that to us. Really, you know, in the interest of seeing if there was a potential for partnership, we put an agreement in place so that we could see that information or that he could share that information with us, and we looked at it. We found it to be completely different. We didn't think it was anything that, you know, was appropriate for us to add into our company, and we also respectfully declined to continue to work with that gentleman

03:24

while he was pursuing that. We wished him the best, and we parted ways at that point, and we ended up -- he had made our Rev. C frames for us, and by the time we went to Rev. D, we had switched to another vendor.

Q. So after the initial communications you had with Brian McPherson and reviewing the NDA, how comfortable did you feel sharing your confidential information with Neovasc?

A. We had no concerns. I had no concerns about it. You know, they had a good reputation in the industry at that point. We had an NDA in place. They had presented the capabilities of their company. It seemed like a great fit. They seemed to pride themselves on service and being a partner to their clients, and so everything felt really good going into it.

Q. How soon after you signed the NDA did you start sharing prototype designs with Neovasc?

A. I think the very next day or maybe even that same day. I'm not sure.

Q. And how often were you communicating with Neovasc once you started sharing prototype designs?

A. It was pretty frequent via e-mail. You know, I'd say we had, and I guess it depended when we got closer to prototypes being ready or not, but we probably had two or three calls a month as things were coming together, and, you know, even more e-mails than that, you know, just sharing information.

Q. Now, on the prototype designs that you used Neovasc to

help assemble, did you hold back any of the engineering details of those designs?
A. No. We were sharing everything that we had, you know, basically in realtime.
Q. And why were you doing that? Why were you so open with them?
A. You know, we wanted to progress our design forward, so we wanted to give them all the information that they needed in order to effectively accurately assemble our implants for us
03:26 and move things along. We were trying to move quickly and with a sense of urgency, and so we didn't want anything to hold us back on that.
Q. So in June of 2009, now you started sending design details of the prototypes that you wanted Neovasc to help you assemble, right?
A. That's correct.
Q. And at that time, which revision were you working on?
A. By the time we had asked them to start working on an assembly, we were on to Rev. C.
03:27 Q. And how many months had you been working on Rev. C already?
A. Again, we had some sketches. I think sometime in the middle of April, but, you know, we were really just starting to get the detail designs ready that we could actually start to have something made, so pretty early on.

Q. So if you turn to Exhibit 1162, please. That may be in the other binder that you have there.
A. Okay.
Q. Can you identify what Exhibit 1162 is, please.
A. It is an e-mail from me to Brian McPherson, Mark Pace-Floridia, and Dr. Quadri.
Q. And Mr. McPherson and Mr. Pace-Floridia are both at Neovasc, right?
A. That's correct.
03:28 Q. And were they both involved in the projects that Neovasc did for CardiAQ?
A. Yes.
Q. And is there an attachment that you sent along with this e-mail?
A. Yes. In this one we had attached a PDF of the flat pattern for this version of the frame.
Q. And is that shown at Page 3? So this is the frame for the Rev. C prototype?
A. That's correct. This is the flat pattern that
03:28 communicates how it's to be laser cut or what the pattern is to laser cut it from a smaller tube. And then once it's laser cut, only that scaffolding that you see there is left. It's kind of rolled up, and then it can be expanded to form.
Q. So you were sending them this flat pattern. At this point had you sent them the actual metal frame that you were going to

have them attach the tissue to?
A. Not yet. This was ahead of that. This particular e-mail was meant to kind of share it just to get initial feedback, and I think in particular we were asking about the eyelet hole size here. We wanted to make sure that the diameter was big enough for their sewers to get their sewing needle through when they attached the frame to it.
Q. Okay, so had you actually made up the metal frames yet?
A. Not yet.
03:29 Q. Had anyone else gotten access to these flat patterns at this time?
A. Just the company that was making the actual frames for us.
Q. Let's turn to Exhibit 1163. Can you identify this, please.
A. This is an e-mail from me to Mark Pace-Floridia at Neovasc copying Brian McPherson.
Q. And did you also include an attachment with this e-mail?
A. Yes, I did.
Q. And what's shown in the attachment?
03:30 A. This is a combination of files. In this particular one, they're SLDPRT parts or file types showing the assembly mandrel tool, the actual detailed three-dimensional model for it in a CAD file, along with some PDFs and other solid parts.
Q. So while we're looking at the description of the attachments up on the screen here, can you explain to us what

types of files these are and what they can be used for.
A. So the SLDPRT files are the nomenclature for three-dimensional models that are made in this CAD software called Solidworks, but it contains all of the dimensional information for a three-dimensional part, so width, thickness, length, everything, all the intricacies. So basically you could 3D print it from there. You could create a detailed print. You could essentially create whatever that product is from that.
03:31 Q. And you mentioned CAD. Is that an acronym for computer --
A. Computer automated drafting.
Q. Okay. And if we advance ahead to Page 5, is that an image of the mandrel?
A. It is.
Q. So in addition to this image then, you're sending all of the underlying engineering details so that Neovasc could actually replicate the mandrel themselves?
A. That's correct.
Q. And why were you doing that?
03:32 A. We had talked to them about potentially using it as an aid when they assembled these prototypes for us just to speed the process along. It was something that Dr. Quadri and I had come up with, and we shared that with them in hopes that it would, you know, advance their efforts there.
Q. And you also sent them a physical mandrel as well, right?

A. Yes.
Q. And there were some patent applications that Dr. Quadri testified about that showed some drawings of the mandrel. Did you ever actually include these CAD files, these engineering files, in the patent applications that you filed?
A. No.
Q. So the drawings were just the line drawings as opposed to the actual --
A. Right, just an illustration as compared to the actual
03:33 dimensions, volumetric model.
Q. And who else besides Neovasc got these kinds of engineering files on the mandrel design?
A. The only company that got the mandrel design was the company that we had sent that model to initially to 3D print the first prototype for us.
Q. Now, did you ever have Neovasc assemble any Rev. C prototypes for you?
A. We did.
Q. And did you have a purchase order in place to set out the
03:33 terms of that relationship?
A. Yes.
Q. And if you turn to Exhibit 1170, which should be in your bigger notebook. Have you got that?
A. Got it.
Q. And can you identify what this is?

A. This is an e-mail from me to Brian McPherson copying Randy Lane and Mark Pace-Floridia.
Q. And it's dated July 2, 2009?
A. That's correct.
Q. And attached to the e-mail, is there a purchase order?
A. There is, along with a number of other attachments.
Q. So if we go to Page 11 of 19 in Exhibit 1170, is this a quote that Neovasc sent you to quote prices to do the work of assembling the Rev. C prototypes?
03:34 A. Yes.
Q. And what were you expecting them to do?
A. So we had talked to them about using the assembly tool. We were going to have them make two more out of stainless steel instead of just the 3D printing material that we had provided, and then 25 hours of assembly development. So once they got the frames, we expected that there was going to be some troubleshooting with the design as they were trying to put it together. Before they could make, you know, the twelve good ones that we asked for here, there would be some assembly
03:35 effort into developing that process.
Q. And after you got that quote, then on the page before it, Page 9, is this the purchase order that you issued to hire Neovasc to do all that work?
A. Yes, it is.
Q. And the "ship to" address on that is in the upper

right-hand corner. What's that address?
A. That's my home address, CardiAQ headquarters.
Q. Okay. And this is based on the information that you had exchanged so far with Neovasc about the Rev. C design, correct?
A. That's correct.
Q. And the prototypes that they were going to assemble were going to be based on your designs for the frames, the metal frames?
A. Yes.
03:35 Q. And how about the tissue portion of it that would be made into the valve, where did that come?
A. We were providing the concept for the tissue design for this valve as well.
Q. And is that also -- is there a pattern, a flat pattern associated with the tissue that's going to be formed into the valve?
A. There is. This is another attachment to this e-mail.
Q. So if we go to Page 12 of 19 in the exhibit, can you tell us what we're seeing here?
03:36 A. This is an engineering print, again, one from a CAD system that has all the dimensions to scale here that can be pulled off and, in this case, used to laser cut this tissue pattern. This was the origami valve concept that Dr. Quadri talked about earlier, where the idea was that you've got all these three leaflets kind of cut with the skirt from a single piece of

pericardial tissue. It can be kind of folded up and stitched along the seams to put this valve together.
Q. So this was the pattern that you were hiring Neovasc to cut the tissue to form the valves themselves?
A. Correct, and we expected that there would be some tweaking required. That was the, you know, assembly development engineering costs associated with it. You know, this is always a bit of engineering and art kind of combined together to tailor the valve.
03:37 Q. And so how did Neovasc get the frames to assemble the tissue to it?
A. We sent those to them.
Q. You had those manufactured from another vendor?
A. Correct.
Q. Okay. And do you recall any issues coming up early on when Neovasc was first assembling the Rev. C prototypes?
A. The first assembly that they showed us, they had just done a mock-up out of cloth. I remember the valve was positioned upside down with respect to the frame, so we just pointed that
03:37 out to them.
Q. Okay, if we turn to Exhibit 26.
A. Okay.
Q. And is this an e-mail from you to Mr. Pace-Floridia at Neovasc?
A. Yes, it is.

Q. And is this referring to the issue with the valve being attached to the frame upside down?
A. Yes. So I just thanked him for the pictures and just made sure he was aware that it was upside down, the inflow was on the outflow side and vice versa, just to make sure that it was corrected for the future prototypes.
Q. And was this the first prototype assembly work that you'd seen Neovasc do?
A. Yes.
03:38 Q. So after this issue, you were saying you had pretty frequent communications with Neovasc by e-mail and phone, right?
A. Yes.
Q. Did you ever have any trouble communicating with Neovasc about the engineering details and designs of the CardiAQ prototypes?
A. No. I think their engineers were always very competent, and I think, you know, we clearly communicated with one another, but there never seemed to be any need for
03:39 clarification. You know, the e-mails were descriptive and well understood, and, you know, we had phone calls when needed to discuss things further, but everything seemed to be clear on their side.
Q. Were they able to work with these CAD files that you had sent them and the other types of computer files relating to the

engineering design of their components?
A. Yes. All the engineers that we were working with, they were well versed in CAD and these programs that we were using on our side as well.
Q. How about mitral valve anatomy, did you talk about these anatomical terms with the Neovasc engineers?
A. In some cases we did. You know, I know Dr. Quadri spoke earlier how he had met with them, you know, in late June to talk about kind of our concept and the mitral anatomy; but, again, you know, we knew that they had been making heart valves for some time, and so we spoke freely about the anatomy to them, and all those aspects were clear, what side was the left atrial side, what side was the left ventricular side, you know, et cetera.
Q. Now, at some point did Neovasc finish assembling the prototype Rev. C frames?
A. They did.
Q. And if you refer to Exhibit 1172, can you identify this for us, please.
A. This is an e-mail from Mr. Lane to me with a few others that Neovasc copied.
Q. And that's dated July 24, 2009?
A. Yes.
Q. And did Mr. Lane give you any feedback about the design itself?

A. He did. If you look at the end there, he just said, "In my opinion, quite an impressive design and assembly."
Q. And did you understand that to be referring to the photographs that were attached to the e-mail?
A. Yes, just the design in general.
Q. And that's the design of this Rev. C prototype?
A. That's correct.
Q. So if we go to Page 5, that's the Rev. C prototype that Neovasc helped assemble?
03:41 A. Yes.
Q. And then Page 6 as well, is that shown there?
A. That's correct.
Q. Okay, if you turn to Exhibit 1179, please. And is this an e-mail from you to Mr. Lane again in August of 2009?
A. Yes.
Q. And can you tell us what's shown in the attachment to this e-mail.
A. This is a mock-up. So once we had received the first Rev. C prototypes from them fully assembled, Dr. Quadri and I
03:42 had some concerns about how the skirt was attached. It was as we had directed them to, but once we got it in our hands, we felt that there would be this need to have that skirt come all the way up like we saw in the earlier illustration of the Rev. C, to come all the way up and over those left ventricular anchors. And so in sort of the way that I was communicating to

them here, I had sketched up a quick mock-up on the computer of what we were thinking, how we wanted to modify the future prototypes that they were still working on, just to make sure that they understood that.

Q. So the red line shown here, what's that representing?

A. Representing the fabric in that lower ventricular skirt region that would come down from the inside of the frame and that what was the diamond section behind that, wrap around to the outside of the left ventricular anchors and come up and

03:43 over the tip to be kind of sewn back on itself to create this full cuff.

Q. So you were making the skirt even bigger than you had described to Neovasc in the original design?

A. That's correct.

Q. And why were you looking to do that? What did you think that would do with respect to anchoring the Rev. C prototype?

A. The desire here, and I think I may have pointed out earlier, but was to have that sort of continuous surface there around the perimeter at that left ventricular anchor tip level

03:43 by having that full cuff, and then also to just make it a little bit more atraumatic at the tip there, but again have that leak prevention as well, so a couple different sort of design intents of making that change.

Q. Okay, I'd like to turn next to another e-mail chain, Exhibit 1183. Can you tell us what this is, please.

A. This is an e-mail, the first one in the chain here from Randy Lane to myself and to Kathleen Hung.
Q. And are you discussing some modifications to the anchors on the Rev. C prototype in this chain?
A. We did. When we had seen the previous ones, it was clear that the left ventricular anchors were a bit too long just as they had come from the frame manufacturer, and we had pointed that out to Neovasc to let them know that we thought we might need to have them trim that as they were making the assembly,
03:44 especially as it relates to having the skirt go up and over it; and we were communicating that to them here, and I wanted to see if they understood that and if they could make that change for us.
Q. So if you go to Page 9 of Exhibit 1183, can you tell us what that is illustrating?
A. Yeah, again, another sort of quick mock-up that I had done on a computer just to communicate the level of where we wanted the two tips from the left atrial side, the anchor tip to meet the tips of the anchors on the left ventricular side. So in
03:45 the versions that they had received, you can imagine that blue line added there just to make it go up to the red line there had gone beyond the tip of the left atrial anchor, so it was kind of running up this way and going past it, and I just was trying to make it clear that we needed to have a gap in there and have them kind of meet the same line so that we could get

the annulus in between.
Q. So what did you do with the assembled Rev. C prototypes once you received them from Neovasc?
A. So these were the prototypes that we ended up using in that August, 2009 first mitral animal series.
Q. And Dr. Quadri was mentioning some of the protocols about getting approval to do that testing. There was an acronym?
A. The IACUC approval.
Q. Can you explain what that means.
03:46 A. So that's essentially, it's the internal animal use and care or animal care and use committee that all of these labs have. It's essentially their internal ethics board that looks at all the protocols that are submitted, makes sure that it's an ethical use of these animals, that all the proper treatments are in place before they approve the study to move forward.
Q. And you attended the animal studies once they were approved?
A. I did.
Q. And what were you doing during the course of those
03:46 studies?
A. So I was there for the duration monitoring, taking video, you know, helping to prep the valves and load the valves, and then really just trying to learn as much as we could from these animal studies.
Q. And what did you observe as to how those Rev. C prototypes

with the full skirt, how did they perform in the studies?
A. As Dr. Quadri pointed out, we saw that they weren't effective at getting a good grip onto the annular ledge and creating that sort of pinching, you know, portion to grab onto.
Q. So if we go to PDX 3.5, does this represent what you observed at those animal studies with the initial implantation?
A. Yes, it does. So we had seen it kind of pop up on the one side there and just couldn't sort of keep it inside the mitral annulus. As it did that, you know, we saw some perforation on
03:47 the left atrial side as it kind of tilted, and, you know, those tips went into the sidewall of the left atrium as well.
Q. So did you consider that a setback?
A. It was definitely a setback. It was -- you know, sort of the natural process of development is, you know, you see these things, and there's all these challenges that we have to try to address, and you sort of figure out -- you know, you learn from it immediately, figure out kind of on the fly what you want to do differently. And that was sort of a theme that, you know, progressed throughout all our development, was kind of trying
03:48 to solve these problems immediately on the back table, and that's where a lot of the learning happened, you know, throughout the history of our company.
Q. So how quickly after you had this setback experience with the initial study did you make any modifications to the Rev. C prototypes?

A. I think we went into the next animal the very next day with the cut version that you saw the video of earlier, where we had gone in between each of those anchors and cut the fabric space so that they could move independently.
Q. So what was the impact of these animal studies on your design of the CardiAQ TMVI product?
A. It changed our whole thinking really on what the sort of effective anchoring mechanism would be. Obviously it didn't change the fact that we had the two sets of opposing anchors.
03:49 It didn't change the fact that we had, you know, this kind of foreshortening action kind of bringing them together; but it changed where we expected to have these ventricular anchors positioned now, having, you know, gone from A to B to C starting out where we thought they were going to be kind of inside these leaflets, and then thinking about having to have them operate freely so that they'd get independently between the cords and behind, so it was a big shift.
Q. Okay. And how about the skirt itself, did it change your thinking about how the skirt was going to work?
03:49 A. It did. I mean, it was the beginning of really recognizing that we didn't need to have that big skirt there. Once we could kind of engage the native leaflets, then we could use that to help create the seal as well.
Q. And did you inform Neovasc that you were doing these animal studies?

A. We had told them that we were having animal studies, yes.
Q. And what did you tell them about the work that they were doing for you after you made this change in the design during the course of these initial animal studies?
A. So we had had that purchase order for the twelve Rev. C frames or Rev. C implants. We had gotten a subset of those before this August animal study, and they were still working on the rest. So I went back to them immediately and said, "Stop what you're doing. We've got to make some changes to this, so
03:50 don't proceed with the ones that you're working on."
Q. Okay, if you turn to Exhibit 1187, can you identify this, please.
A. This is an e-mail that I had sent to Brian McPherson on August 20.
Q. And was this where you told him not to make any more of those Rev. C prototypes?
A. It is. This is actually in the middle of the trial, so when I sent this, I think we were still in Minneapolis and mentioned that it was going well, "But in the meantime, don't do anything more for the remaining six valves." I didn't expect the tissue valve to change, but we knew that we were going to make other changes."
Q. If you turn to Exhibit 1188 in your notebook, can you tell us what that is, please.
A. This is an e-mail that I had sent to Kathleen Hung on

Monday, August 31, 2009.
Q. And was she asking how the animal results came out at the bottom of her e-mail on Page 2 of this document?
A. She did. In her original e-mail, she said, "We all look forward to hearing your animal results as well as helping with prototypes in the future."
Q. And did you share information with her about that?
A. We did. You know, we went back to her there and said we needed to get some of the prototypes back. Based on some of
03:52 the things that we learned during that August study, we wanted to go back and do acute animals in September. And we only had a couple weeks in between there, and so we didn't have time to go back and get more frames made. It was too quick of a turnaround in the time that it required to get back into the animal lab and when they had availability. So we asked her to send some of the frames back so that Dr. Quadri and I could kind of modify those in his basement, essentially, to get them at a level where we thought we could address the learnings that we had from the August study.
03:52 Q. So in this e-mail chain, were you telling Neovasc about the changes in the Rev. C frame that you were planning to make?
A. In this particular one, I think we just asked them to send them back to us, so we weren't telling them right here, I don't think.
Q. If we go to the top e-mail there, you're referring to

lowering the height of the frame?
A. We did tell them, yes, as I see it now, so I wasn't reading the whole thing, but, yeah, we wanted to lower the height of the frame and lower the valve placement, and we wanted to replace the fabric skirt.
Q. So, now, you were not going through another design cycle by going back to the stent manufacturer to make new frames, are you?
A. That's correct. We wanted to sort of bypass that, this
03:53 cycle, and see what we could do to work with the Rev. C frames that we had, but we knew that it was going to require some kind of trial and error with Dr. Quadri and I sort of, again, kind of learning on the fly and just trying a few things, you know, together to get these Rev. Cs sort of refined so that we could go back into animals and continue to learn quickly.
Q. And did you think that doing those design modifications yourselves on the Rev. C frames was going to affect how quickly you could test these designs again?
A. We did? I mean, you know, I think we had good vendors
03:53 that we were working with, but, you know, we needed to be able to move quickly; and as a two-person company and working, you know, kind of side by side in his basement, we could, you know, burn through a lot of different concepts and, you know, kind of optimize quickly on the fly.
Q. Okay. And did you go back and do more animal studies with

those modified Rev. C frames?
A. We did. So in mid-September, 2009, we went back and did more animals.
Q. Is Exhibit 14-8 another one of your lab notebooks?
A. I'm sorry, 14-8?
Q. 1408.
A. Oh, 1408. Yes.
Q. And can you go to the Page No. 122, and can you tell us what the notes refer to here?
03:55 A. Yes. These are just some sketches of what we had done to modify the Rev. C heading into that next study. So what you see on the top left there represents the, I guess, original Rev. C frame. We knew from that first study that the valve was sitting too high in the atrium, so one of the things that you see on the right-hand side there is this dotted line where we had intended to cut off the top of the device and make it lower. We didn't have the valve sitting in that region, and so we just wanted to remove it, get the height lower. And then we had also seen that there was too much motion as well in the
03:55 course of the other learnings, and so we sacrificed one Rev. C frame to just get that oval-only section that you see in the middle there so that we could reinforce the lower portion of the ventricular side because it didn't have the stiffness that we needed to satisfy the dynamic forces in the mitral annulus. So we sewed those together. I think in one case we used

sutures. In another case it was wire form that we just kind of twisted it together on the notes there. And then on the lower section there, you see the bovine tissue valve but no fabric on the skirt. It's also made of bovine, and it's attaching to the eyelets down at the bottom, so we're going down covering that lower section of that new diamond area that we added just at the lowest portion of the modified valve, and just coming up to the very bottom of the left ventricular anchor so that that whole top section is exposed now.

03:56 Q. Can you point that out to us. Where are the exposed anchors in this sketch?

A. All this length is exposed anchors, so this full length would be exposed now. Just as we add this length, the skirt is going to come down here and come up over that, and that's what you see kind of blown up down here.

Q. Okay, and did you use these modified Rev. C designs in additional animal studies in September?

A. We did.

Q. And how were the results there?

03:57 A. The results were very good. We were able to confirm, and as you saw earlier from some of the videos, but confirm that we were able to get that new kind of fixation action where we were going, you know, between the cords, the leaflet, and behind to the opposite side, that we could, you know, start to engage better. It had a number of advantages in terms of anchoring,

you know, by the annular contact, but also using the tension in the cords to dissipate that load, and then also using the native leaflets to seal around the perimeter instead of relying on that skirt for it.

Q. Did you have any discussions with anyone at Neovasc about those animal studies?

A. We had phone calls afterwards just describing, you know, what we had done to modify the valves. I don't recall exactly what was discussed there. And then we met with Neovasc in

03:57 person -- it was the first time I had met with anybody from Neovasc in person -- at the TCT Conference, that Transcatheter Therapies Conference in September of that year.

Q. So did you change the design of the TMVI frames based on the experiences that you had at those animal studies?

A. We did, so, you know, as soon as we got back from that, and I think the conference was immediately after, so as soon as we got back from the conference, we started thinking about what we were going to do for the next revision, which would be Rev. D, and that started kind of in early October.

03:58 THE COURT: Is this a good stopping place, Mr. Sganga?

MR. SGANGA: Sure, your Honor. We're on to a new rev, and this would be a convenient place to stop before we get into it.

THE COURT: Okay. So, members of the jury, thank you for your attention today. Keep an open mind. Don't talk to

anyone, watch what you do on social media. We'll see you back at 10:00 o'clock tomorrow.

Just one more thing on the lunch topic. I know you guys have expressed an interest in having lunch in the jury room. Not every jury gets lunch. It needs to be justified so the taxpayers are buying you lunch for a sufficient reason, and we call that sort of a semi-sequestration order. That's because there's so many lawyers in the courthouse, and we want to make sure you're somewhat insulated from them. So the flip 03:59 side of that coin is, you kind of can't have it both ways. You can't say you need to have it private to have lunch but you can still roam around. So if you decide you want to have lunch in the jury room, you have to largely stay in that area during lunch and your snack breaks. If you want to run outside for a phone call or if any of you smoke, that's okay, but you would be largely confined to that area. So we're going to go ahead and get you lunch for tomorrow and see how that works out. If you decide you're feeling overly caged, let us know, and we can revisit it. I know there's also a scheduling request for next 03:59 Tuesday. I'll bring that up with the parties tomorrow as well.

All right, have a good night everyone.

THE CLERK: All rise for the jury.

(Jury excused.)

THE COURT: Okay, we have the exhibits to take care of. You just heard me allude to, one of the jurors has a

doctor's appointment on Tuesday at 3:00, has a doctor's appointment and has to leave Tuesday at 3:00, and I was hoping -- I don't want to lose that hour, so I was hoping we could start, go 9:00 to 3:00 that day? Does that work for everybody?

MR. SGANGA: Yes, your Honor.

THE COURT: All right, I'll double-check with the jurors tomorrow.

How about the exhibits? Do you want to do those now? Or we can do them first thing tomorrow morning too.

MS. LEA: I'm happy to do them now, your Honor. The plaintiffs would like to move into evidence, and I have them in the order that they were called in the case, Exhibit 1360, 328, 1442, 1374, 1445, 1007, 1395, 2634, 615, 2173, 565, 1458. That's all I have.

MR. BOEHM: No objection.

(Exhibits 1360, 328, 1442, 1374, 1445, 1007, 1395, 2634, 615, 2173, 565, 1458 received in evidence.)

MR. BASKIN: The defendants would like to move in exhibits for cross, 5024, 5004, 263, 260, 261, 265, 266, 271, and 552.

THE COURT: Okay.

(Exhibits 5024, 5004, 263, 260, 261, 265, 266, 271, and 552 received in evidence.)

THE COURT: Okay, we have some technical issues to

take care of now, I guess, on the sound system, Phil. I'm going to put you on this. Apparently the courtroom below us is complaining about ceiling noise. I will leave that to others to work out.

Anything else for today?

MR. FLYNN: Your Honor, may we make a suggestion on lunch?

THE COURT: Yes.

MR. FLYNN: The last time that we have been in a carnival that has lasted this long, the parties split the cost of providing lunch for the jurors, which would free us of the taxpayer issue.

THE COURT: I have no idea what the answer to that is. So you want to pay for their lunch so they can --

MR. FLYNN: We'll take care of paying for it so if they want to wander in the hallway.

THE COURT: Okay, let me think about that and talk to the lunch experts in this courthouse, which I am not one.

I'll be out early tomorrow. I have a scheduling conference in another case right now, so I'm happy to talk to you about anything we can accomplish quickly, but other than that, we can save it till the morning.

MR. GRAVES: I have been informed, your Honor, by local counsel that we should be standing up to make objections rather than sitting down, so we'll start to do that tomorrow.

THE COURT: It's not -- is Mr. Rosen here? It's not important to me. I don't feel disrespected --

MR. GRAVES: Okay, thank you.

THE COURT: -- by that.

(Laughter.)

THE COURT: All right, I'll see everyone tomorrow.

(Adjourned, 4:04 p.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

We, Debra M. Joyce, Kelly Mortellite, and Lee A. Marzilli Official Federal Court Reporters, do hereby certify that the foregoing transcript was recorded by us stenographically at the time and place aforesaid in Civil Action No. 14-12405-ADB, CardiAQ Technologies, Inc. v. Neovasc Inc., et al, and thereafter by us reduced to typewriting, and is a true and accurate record of the proceedings.

Dated this 4th day of May, 2016.

/s/ Debra M. Joyce

/s/ Kelly Mortellite

/s/ Lee A. Marzilli, RPR, CRR